Escuela de Ingeniería y Arquitectura Universidad Zaragoza

Escuela de Ingeniería y Arquitectura

Analytical guide of the changes suggested by Directive 2006/42/EC on the safety of machines

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Abstract

This thesis talks about the different changes that are suggested by the new Directive 2006/42/EC from the last one 98/37/EC. Changes like legal responsabilities, way to makes a risk evaluations and what kind of problems and how to solve, examples of documentation and how to fill it and more topics about this new Directive.

The new Directive was effective from 29 of December of 2009. Time between 2006 and 2009 was time to makes changes at machines and manufacturers adapt their machines to the new Directive.
These Directives was created by the European Comision, and later Parliament and European council pass this texts like Directives for European standarization. This Directive 2006/42/EC is created for the use of the different countries of Europe. Countries included are the 27 countries that take part at the European Union and also Liechtenstein, Island and Norway.

One of the most important changes suggested by this Directive is that in the case of noone know who is the manufacturer of the machines, automately the owner at that moments is going to has the legal responsability of that machine.

Many devices are included in this new one Directive but the main difference is the inclusion of Lifts. Also many devices are excluded from the scope of the Directive like electric and electronic devices and high voltage equipments as well.

Is very important to talk about standards, because are the way to make a machine or equipment safety and after that know what kind of options can you take to be sure that a machines is safety or in the wort case what is the grade of damage that the machine can give to us.

At the last part of this Thesis I uncluded squematic examples of the different electronic devices that are used for the safety at machines.

Keywords Changes safety machine directive

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Tiivistelmä

Tämä työ käsittelee erilaisia muutoksia uuden Direktiivin 2006/42/EC ja vanhan Direktiivin 98/37/EC välillä. Käsittelen aiheita tavat tehdä riskiarvioita, erilaiset ongelmat ja ratkaisut, esimerkkejä dokumentoinnista ja muuta tietoa uudesta direktiivistä.

Uusi direktiivi astui voimaan 29. Joulukuuta 2009. Vuosien 2006 ja 2009 välisenä aikana valmistajien tuli muokata koneista uuden direktiivin mukaisia.
Direktiivi valmisteltiin Euroopan komissiossa ja myöhemmin Euroopan parlamentti ja Eurooppa-neuvosto hyväksyi sen. Direktiivi on luotu useiden eri maiden käyttöön Euroopassa. Direktiivi on käytössä EU-maiden lisäksi Liechtensteinissä, Islannissa ja Norjassa.

Yksi tärkeimpiä ehdotuksia tässä direktiivissä on, että jos koneen valmistajaa ei tiedetä on koneen senhetkinen omistaja laillisesti vastuussa kyseisestä koneesta.

Monia laitetta on lisätty direktiivin piiriin, mutta tärkein muutos on hissien liittäminen direktiiviin. Myös monia laitteita on suljettu soveltamisalan ulkopuolelle kuten sähkölaitteet, elektroniset laitteet ja korkeajännite varusteet.

On erittäin tärkeää puhua standardeista koska sillä tavoin saadaan koneista ja varusteista turvallisempia. Lisäksi käyttäjä tietää minkälaisilla asetuksilla kone on turvallinen sekä tiedetään minkälaista vahinkoa kone voi aiheuttaa pahimmassa tapauksessa.

Viimeisessä osiossa esittelen esimerkki kaavioita erilaisista elektronisista turvalaitteista koneissa.

Avainsanat Muutokset turvallisuus kone direktiivi

Summary

INTRODUCTION

RULES/ DIRECTIVES STRUCTURE.

About the ``Rome treated´´, the European Council has issued directives for the elimination trade obstacles and the free circulation of products inside Europe. These directives consist of product directives, substantiated at the 10th article, today article 95, and work directives, substantiated at the 118th article, today 138.

These directives, like 2006/42/EC are approved by the European Parliament.

Consequently, the governments of the European countries have to transpose these directives to their jurisdiction.

DIRECTIVES, HAZARDS AND LAWS.

Due to that the different national standards don't represent trade obstacles, should allow the free circulation of the goods inside EU. However, there isn't a legal obligation about the respect of the standards and harmonized standards. Therefore, in the case of not comply the harmonized standards, the manufacturer can show that the target had been respect. The manufacturer can work by them own responsibilities if the measure is as safe as the EC harmonized standards. However, the fact of apply that harmonized standards has the advantage of ``legal presumption about the conformance test´´, it means, the authority (court, prosecution...) has to demonstrated the opposite.

In the case of not comply harmonized standards, the manufacturer has to demonstrate that the basics legal requirements have complied.

LEGAL SITUATION.

European Commission has the initiative right and in consequently they propose legal texts which are put to the vote at Parliament and Council. Like an executive branch, it realize the execution of all European laws (directives, regulation, resolutions), of the budgets and the approved programs by the Council and Parliament.

As main deliberative organ of the European Union, Council is the legislative organ of the Union; in coordination with the European Parliament it plays it competence to legislate in different community settings. Ensures for the global economic politic coordination of the member states.

European Parliament is the democratic representation of 374 million of European citizens. Share the legislative function of the Council, it means, the approve of the European laws (directives, regulation, resolutions). This participation at the legislative activities guarantees the democratic legitimacy of the approved texts.

By the 100 article of the treaty for the European Constitution, directives and regulations made by this way are converted in European Rights. These standards are directed to the governments of the EU stages and are published at the ``Official Diary of the EU´´, for example, Directive 2006/42/EC was published at the DUOE (Official Diary of the European Union) at the date of 9-6-2006. The numeric combination has this meaning: **42** mean the number of Directive of the **E**uropean **C**ommunity and **2006** the published year.

After this step, governments of the different countries should proportionate to them national legal framework, due to we are holding to the national jurisprudence.

FIGURE 1. European Union Brand.

CHAPTER 1. DIFFERENCES BETWEEN USER DIRECTIVE AND MANUFACTURE DIRECTIVE

Fundamentally we can find two kind of directives about the safety at machines:

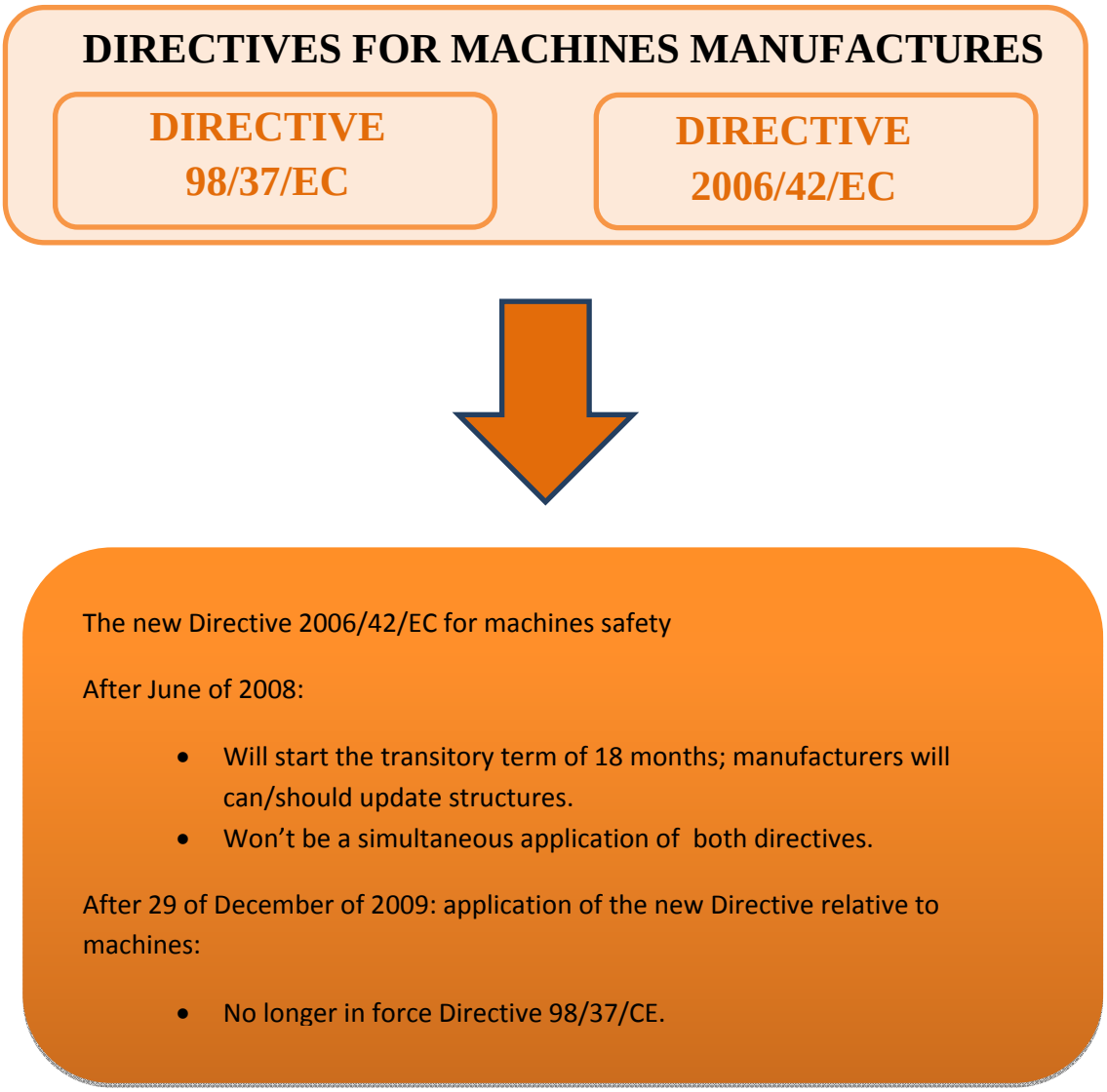


FIGURE 2. Squema about changes between Directive 98/37/EC and Directive 2006/42/EC.

DIRECTIVES FOR MACHINES USERS

DIRECTIVE 89/655/EEC

DIRECTIVE 95/63/EC

DIRECTIVE 2001/45/EC

The new Directive 2001/45/EC for machines users.

- It give new reading to the point 6 of chapter 1 of annex I
- Introduce the paragraph 4 at the annex II
- Repealed certain provisions included in various standards and referred mainly to scaffolds

FIGURE 3. Squema about changes between Directive 98/37/EC and Directive 2006/42/EC.

The fundamental obligation of a machine manufacture is the comply of the Directive 98/37/EC which after 29 of December of 2009 is going to be the new Directive 2006/42/EC.

The entrepreneur who exerts like a user has one fundamental obligation:

- If the entrepreneur acquires new manufacturing equipment, is bound that them have to be certificates by the Directive 98/37/EC or Directive 2006/42/EC if he acquire a new manufacturing equipment after 29 of December of 2009.

Must be taken in account that CE marked don't means that the equipment is safety, that's why the entrepreneur has to verify the minimum security provisions.

CHAPTER 2. NEW MACHINES DIRECTIVE (2006/42/EC)

1. Legal analysis

OLD REFERENCES:

- Transpose the Directive 2006/42/EC

NOTES:

- Entry into force were 29 of December of 2009
- Effects of the repeal of that Directive were immediately

ELEMENTS:

- Lift devices
- Harmonization of laws
- Cables
- Marketing
- Work equipment's
- Machinery
- Conformity mark EC
- Normalization
- Safety and healthy at the work
- Industrial safety

The new Directive 2006/42/EC of machinery:

- **From June of 2006**: Start the transposition time during 24 months in all of the Member Stages
- **From June of 2008:** Starts the national transposition time during 18 months; manufacturers should update the structures
- **From 29 of December in 2009:** Application of the new machinery Directive: Directive 98/37/Ewes outdated

FIGURE 4. Dates to start the new Directive 2006/42/EC.

COMPARATIVE BETWEEN OLD AND NEW DIRECTIVE	
DIRECTIVE 98/37/EC	**DIRECTIVE 2006/42/EC**
• Preamble with 25 recitals • 16 articles in 4 chapters • 9 annexes	• Preamble with 30 recitals • 29 articles • 11 annexes

TABLE 1. Comparative between old and new Directive.

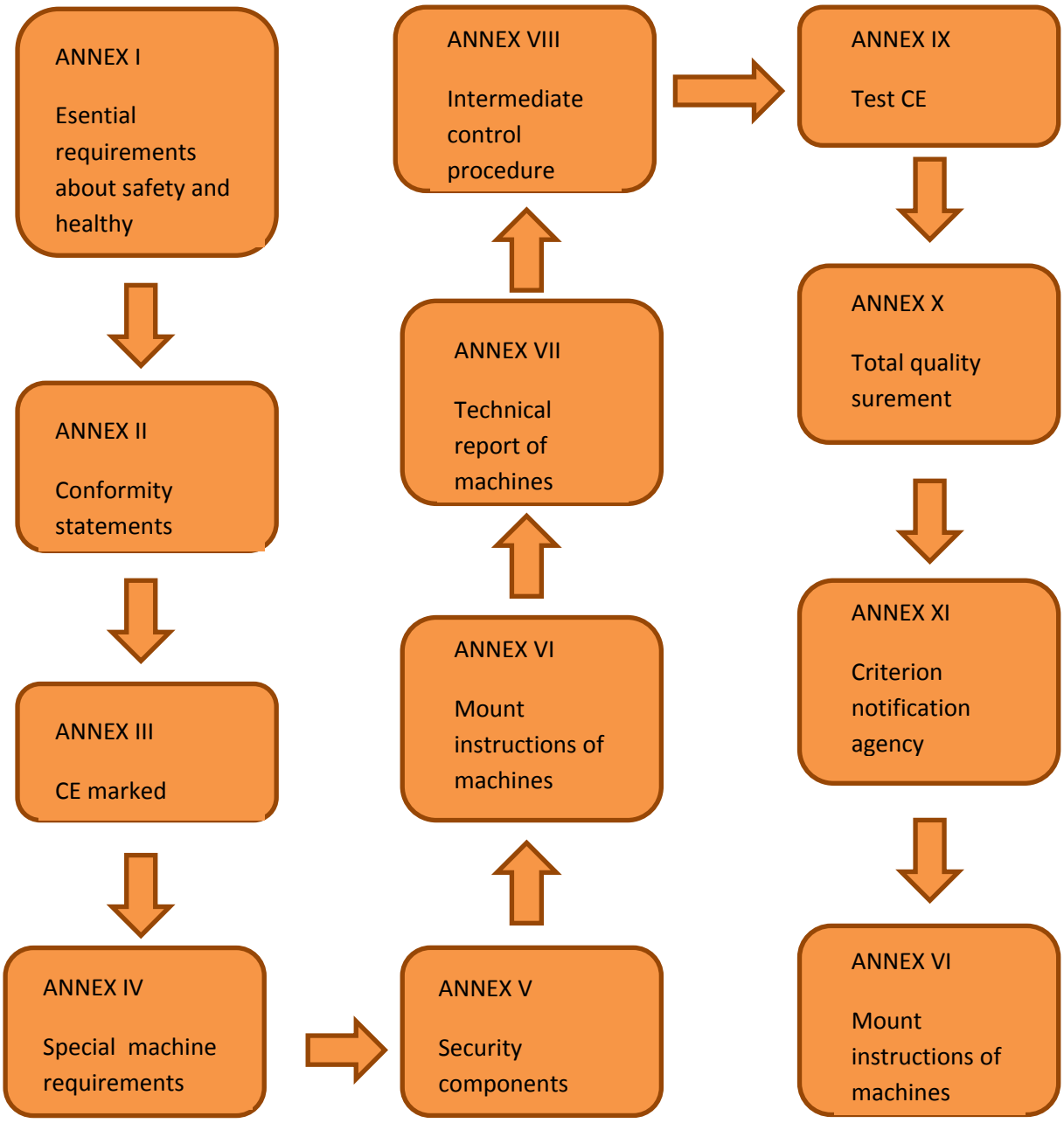


FIGURE 5. Annexes of the Directive 2006/42/EC.

2. Territorial scope for the application of the new directive

The new Directive is beginning in all European countries which take part at the European Union (27 countries), including Romania and Bulgaria from 2007 and also Switzerland, Island, Liechtenstein and Norway. This community of 31 countries is going to be denominated like EES (European Economical Space).

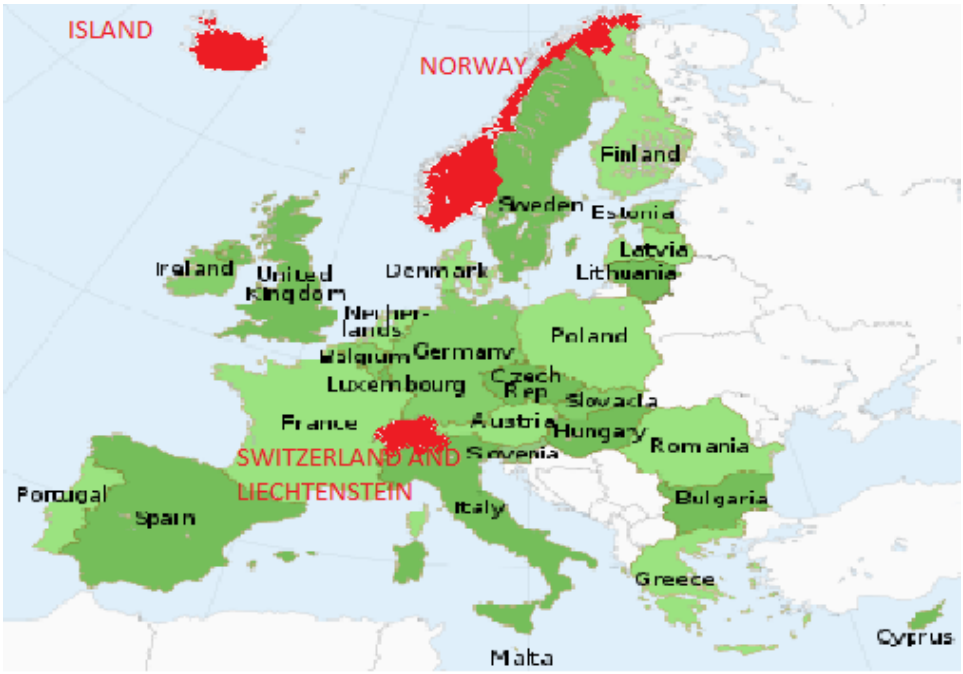


FIGURE 6.Application scope of the Directive 2006/42/EC.

3. Scope for the technic application of the new directive

The scope for the technic application of the new directive is:

- Machines
- Interchangeable equipment
- Safety components
- Lift accessories
- Chains, ropes and webbing
- Removable devices of mechanic transmission
- Partly completed machinery
- Hoists for the lift of people of people and materials

With this new Directive, lifts are totally include and will have to comply all the requirements and conditions for machines. This one means that all machines that have the same function of lifts at work have to comply also all the same rules of them.

From the point of view about legal systematic, in the future will be only machines and quasi machines, consequently two declarations: from one hand the EC in according to annex II A and on the other hand the incorporation declaration of quasi machines in according to annex II B.

In the future the EC declaration will be used by the products which being inside the Directive, like safety components.

3.1 Excluded from the application scope

In the new Directive there are more specifications about **machines or hardware** which are excluded from the application scope. These are:

- Safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery.
- Specific equipment which are going to use at fairs and amusement parks.
- Machines specific for nuclear uses and which fails can emit radioactivity.
- Arms, included fire arms.
- Seagoing vessels and mobile offshore units, and machinery installed on board such vessels and units.
- Machines designed or manufacturing to military or police use.
- Machines designed or manufacturing which will be temporary used in laboratories.
- Lifts at mine wells.
- Machines which are used to lift actors at artistic representations.

Are excluded of application these **electrical and electronic** products:

- Appliances
- Audiovisual equipment
- Information technology equipment
- Office machines
- Connection apparatus and low voltage control
- Electric engines

Are excluded also **high voltage equipment**:

- Connection apparatus and low voltage control
- Transformers

About **transport** are excluded:

- Agricultural and forestry tractors for the risks covered by the Directive 2003/37/EC are excluded machines installed inside them.
- Motor vehicles and their trailers covered by Directive 70/150/CEE, of 6 of February in 1970 about homologation of engine vehicles and their trailers. Are excluded machines installed inside them?
- Vehicles covered by Directive 2002/24/EC of Parliament and Council, of 18 of March in 2002 about homologation of engine vehicles with two or three wheels, and their modifications. Are excluded machines installed inside them?
- Engine vehicles which are used only for competition.
- Air, water and rail transports, with exclusion of machines that are installed inside them.

3.2 Machine definition

- An assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application,
- An assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion,
- An assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure,
- Assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole,
- An assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;

FIGURE 7.Machine.

3.3 Partly completed machinery definition

Assemblies which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies.

3.4 Interchangeable equipment definition

A device which, after the putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool.

3.5 Safety component definition

Are the components which serve to fulfill a safety function?

- which is independently placed on the market,
- the failure and/or malfunction of which endangers the safety of persons, and
- Which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.

3.6 Lifting accessory definition

Component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market;

slings and their components are also regarded as lifting accessories.

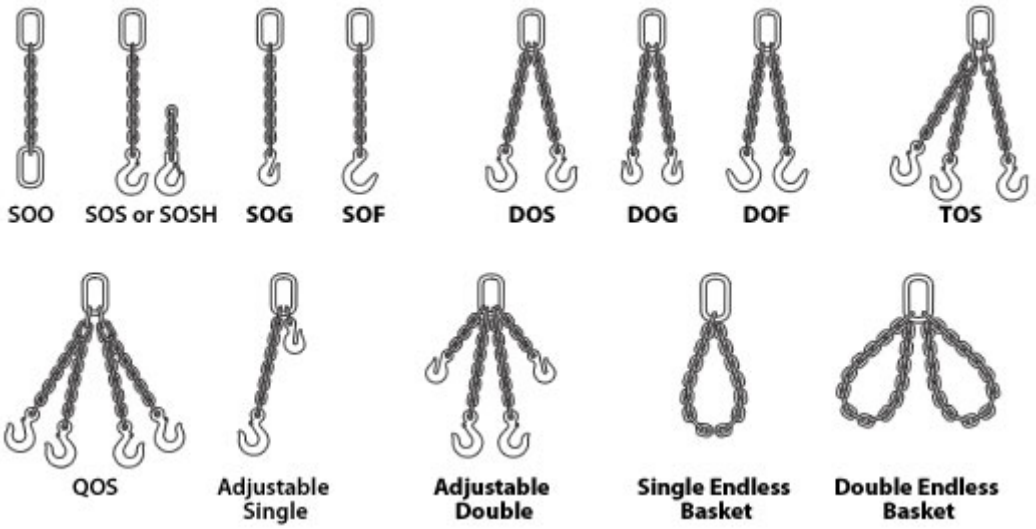


FIGURE 8. Different lifting accessories.

3.7 Boilers ropes and webbing definition

Are designed for lifting purposes as part of lifting machinery or lifting accessories.

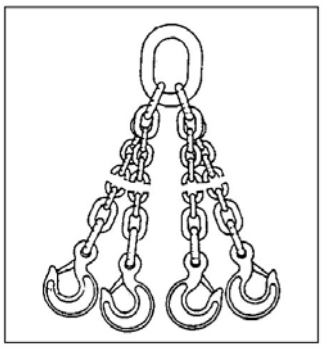


FIGURE 9. Boilers.

3.8 Removable mechanical transmission device definition

A removable component for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one product.

4. Partly completed machinery

In according to the definition, the partly completed machinery has not undergone an assembly process so long as that it can perform by itself a particular application, including management and safe operation of the same. In these levels, it is left to the next level of the value creation chain, making a safety and complete machine which comply all the conditions set by the Directive. So, the partly completed machinery manufacturer or agent are exempt from the comply of other obligations that the Directive don't set (in exception of the manufacturer declaration).

A consequence of the new policy is that this will mean a significant increase in work in each of the cases.

FIGURE 10. Partly completed machine.

Through individual provisions is stabled that the machines must also be safe, to the extent that is feasible, and that in this case, the manufacturer has also allocated the relevant documentation and reporting obligations. In this sense, it will not be necessary in the future to adopt any contractual arrangement individual or voluntary.

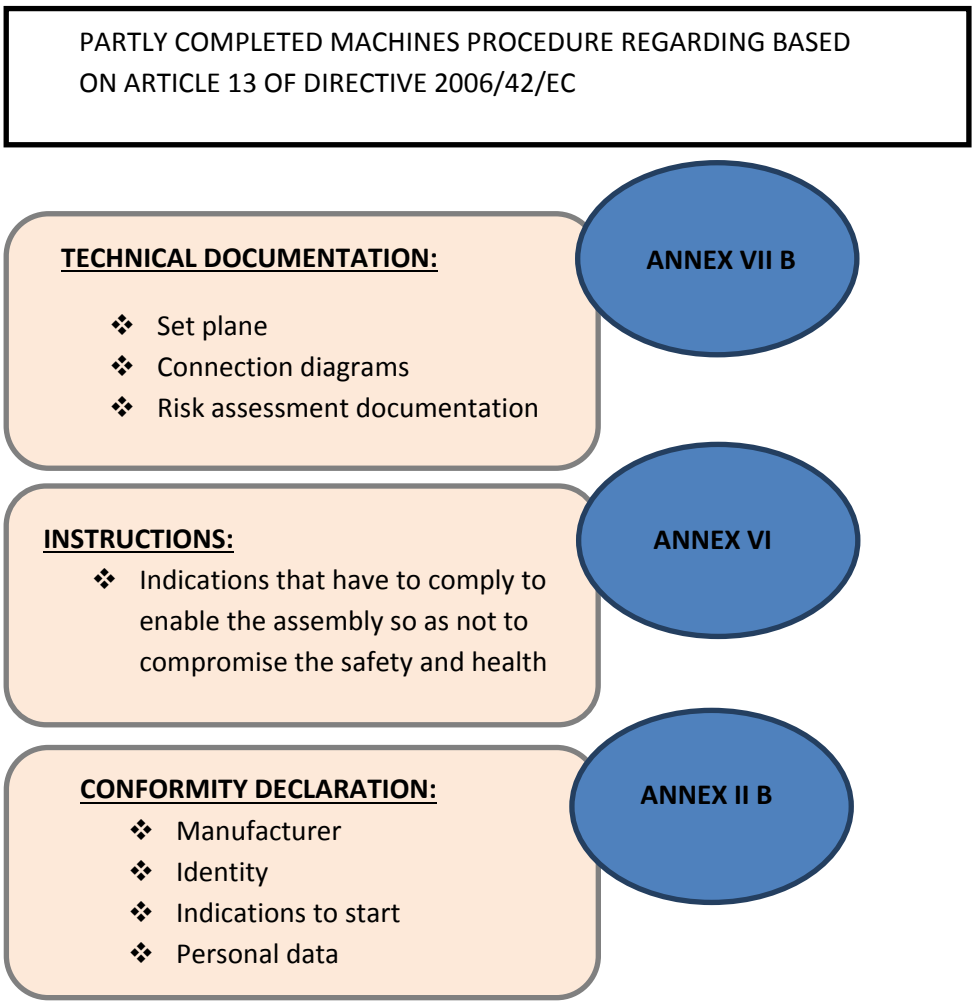


FIGURE 11. Partly completed machines procedure regarding based on article 13 of Directive 2006/42/EC.

In the future, machines manufactures must comply the next three requirements according to the Directive.

1. PREPARE TECHNICAL DOCUMENTATION:

The content of the technical documentation to develop are defined at the VIIB Annex of the Directive.

Seeing the extend of documentation to prepare (risk test, comply safety object according to the annex I,), is clear that the manufacturer of a partly completed machine have the same obligations like a manufacturer of a machine.

2. MOUNTING INSTRUCTIONS.

Mounting instructions of a partly completed machine are similar of the instructions manual for the working of a machine but these instructions must be clearer.

Mounting instructions can be writing in the language that the customer wants, and this is the most difference to the instructions manual.

3. INCORPORATION DECLARATION

Content and structure of the incorporation declaration are included at annex II B of Directive. Subject commissioning is maintaining, known as the manufacturer's declaration of force today.

Attach the statement is recommended as an annex, if applicable, as Annex I of Directive, and describe here that security objectives have been addressed in the design and manufacture of the partly completed machinery.

In the case of a manufacturer manufacture partly completed machines in series, is going to apply also the requirement of a quality assurance system at Annex X.

The declaration of incorporation must contain the following particulars:

1. Business name and full address of the manufacturer of the partly completed machinery and, where appropriate, his authorised representative;

2. Name and address of the person authorised to compile the relevant technical documentation, which must be established in the Community;

3. Description and identification of the partly completed machinery including generic denomination, function, model, type, serial number and commercial name;

4. A sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives. These references must be those of the texts published in the *Official Journal of the European Union;*

5. An undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery;

6. A statement that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of this Directive, where appropriate;

7. The place and date of the declaration;

8. The identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

Declaration of incorporation according to the EC Machinery Directive 2006/ 42/ EC, Appendix II B

Manufacturer:

CENTA Antriebe
Kirschey GmbH
Bergische Strasse 7
42781 Haan / GERMANY

Contact:

Phone +49-2129-912-0
Fax +49-2129-2790
centa@centa.de
www.centa.info

We herewith declare that the **incomplete** machine

Product:	Centrifugal clutch CENTASTART
Model / series code:	CS / 0060
Installation size:	80..2500
Design:	all
Serial number:	according to shipping documents, if applicable

- provided this is possible as far as the scope of supply is concerned - complies with the following basic requirements of the **Machinery Directive 2006/ 42/ EC** Appendix I, subchapters 1.1.2, 1.1.3, 1.1.5, 1.3.2, 1.3.3, 1.3.4 and 1.5.4.

In addition, we declare that the special technical documents for this incomplete machine were compiled according to Appendix VII Part B and undertake to forward these to the market monitoring authorities by request via our "Documentation Department".

Commissioning of the incomplete machine is interdicted until the incomplete machine has been incorporated in a machine and the latter complies with the provisions of the EC Machinery Directive and the EC Declaration of Conformity according to Appendix II A is on hand.

The declaration is invalidated by every modification to the delivered parts.

Authorised representative for the compilation of the relevant technical documents:

i.A. S. Anderseck

by order of Gunnar Anderseck
(Authorised Person Documentation)

Declaration of incorporation was issued:

i.V. J. Exner

Haan, 11.12.2009

by proxy Dipl.-Ing. Jochen Exner
(Design Management)

FIGURE 12. Example of Declaration of incorporation.

5. Security components

Definition about security components is the same that before I have written.

In the future, security components must be accompanied with the **instruction manual in the language of the country** where it will be used.

According to security components, there is another **annex V** only to inform, which contains an indicative list with the security components.

Security components list is this one:

1. Guards for removable mechanical transmission devices.

2. Protective devices designed to detect the presence of persons.

3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in items 9, 10 and 11 of Annex IV.

4. Logic units to ensure safety functions.

5. Valves with additional means for failure detection intended for the control of dangerous movements on machinery.

6. Extraction systems for machinery emissions.

7. Guards and protective devices designed to protect persons against moving parts involved in the process on the machinery.

8. Monitoring devices for loading and movement control in lifting machinery.

9. Restraint systems to keep persons on their seats.

10. Emergency stop devices.

11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.

12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex I.

13. Systems and devices to reduce the emission of noise and vibrations.

14. Roll-over protective structures (ROPS).

15. Falling-object protective structures (FOPS).

16. Two-hand control devices.

17. Components for machinery designed for lifting and/or lowering persons between different landings and included in the following list:

(a) devices for locking landing doors;

(b) devices to prevent the load-carrying unit from falling or unchecked upwards movement;

(c) over speed limitation devices;

(d) energy-accumulating shock absorbers,

— non-linear, or

— with damping of the return movement;

(e) energy-dissipating shock absorbers;

(f) safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls;

(g) electric safety devices in the form of safety switches containing electronic components.

6. Responsibilities

No content change respect from Directive 98/37/EC. There are differences between manufacturers who reside at European Union or agent who reside at European Union, and manufacturers from a 3th country, who are responsible to comply the Directive obligations.

Are responsible of Directive conformity:

• Manufacturer (authority agent)
• Who grouping machines or machines components
• Who manufacture machines for own use
• Who import machines from another country of the European Economic Area
• Machine operator (becomes manufacturer) when he: ✓ Remodel the machine (*substantially* modified) ✓ Assembles installations ✓ Complete machines
• Who *substantially* modified machines with the incorporation or modification of components
• Who *substantially* modified used machines and give to other people

TABLE 2. Responsible of Directive.

In the case of the legal responsible can't be found, then manufacturer is considered everyone who has marketed or put into operation the machine.

In the future, must be included at the declarations (in the conformity declaration for machines and in incorporation declaration for partly completed machines) a person with home at the Economical European Area, who can recompile technical documentation in according to annex VII.

6.1 Market surveillance – article 4

1. Member States shall take all appropriate measures to ensure that machinery may be placed on the market and/or put into service only if it satisfies the relevant provisions of this Directive and does not endanger the health and safety of persons and, where appropriate, domestic animals or property, when properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen.

2. Member States shall take all appropriate measures to ensure that partly completed machinery can be placed on the market only if it satisfies the relevant provisions of this Directive .

3. Member States shall institute or appoint the competent authorities to monitor the conformity of machinery and partly completed machinery with the provisions set out in paragraphs 1 and 2.

4. Member States shall define the tasks, organization and powers of the competent authorities referred to in paragraph 3 and shall notify the Commission and other Member States thereof and also of any subsequent amendment.

7. Annex I. News

The most relevant part of the directive which is technical security hasn't got changes, only modifications to adapt it to the EN ISO 12100.

Before marketing or working machines, manufacturers or autoricez agent, should assure that this machine comply the elementary healthy and safety requirements that are at annex I

FIGURE 13.Relevant information about Directive 2006/42EC.

Mainly it include the following general instructions:

- ✓ Has remained all the structure of Annex I.
- ✓ Has remained new requirements for new products.
- ✓ Some requirements have been clarified, expanded or reinforced.
- ✓ Terminology is now adapted to the standard EN ISO 12100.

The structure of Annex I is the following:

- ✓ General principles
- ✓ General requirements
- ✓ Specific requirements to:
  - Some machines categories
  - Risk due to machines mobility
  - Risk due to lifting movements
  - Machines that are using for underground works
  - Machines which present particular hazards due to lifting persons

7.1 General beginnings. News

I am going to foreground this fragment:

``....It is essential to examine the whole of this Annex in order to be sure of meeting all the relevant essential requirements. When machinery is being designed, the requirements of the general part and the requirements of one or more of the other parts shall be taken into account, depending on the results of the risk assessment carried out in accordance with point 1 of these General Principles.´´

At Directive is being clarify the evaluation process and risk reduction that the manufacturer must to do.

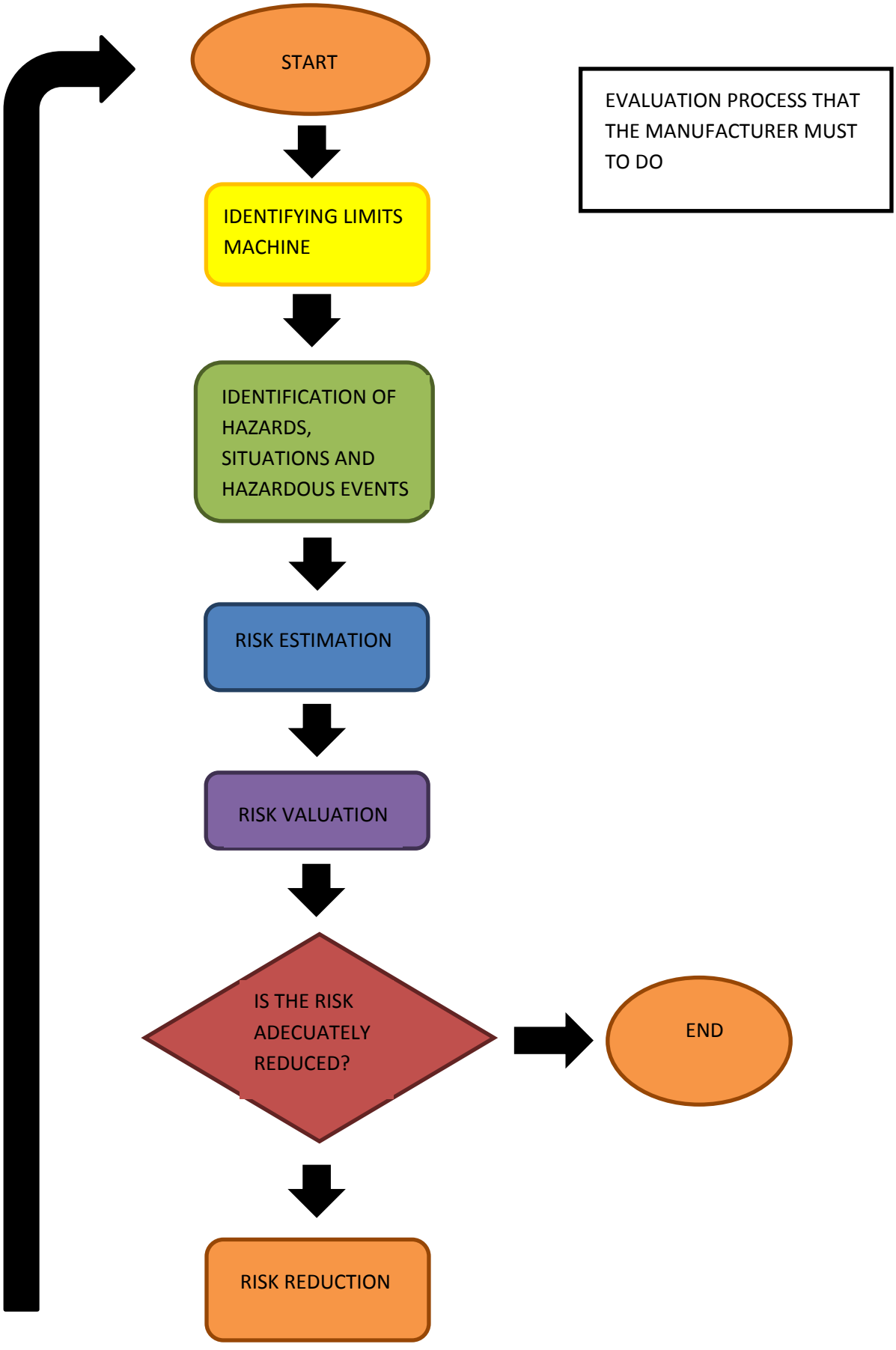


FIGURE 14. Char about risk evaluation.

These definition are established:

- **‘hazard’** means a potential source of injury or damage to health;
- ‘**danger zone’** means any zone within and/or around machinery in which a person is subject to a risk to his health or safety;
- ‘**exposed person’** means any person wholly or partially in a danger zone;
- **‘operator’** means the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving machinery;
- **‘risk’** means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation;
- **‘guard’** means a part of the machinery used specifically to provide protection by means of a physical barrier;
- **‘protective device’** means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard;
- **‘intended use’** means the use of machinery in accordance with the information provided in the instructions for use;
- **‘reasonably foreseeable misuse’** means the use of machinery in a way not intended in the instructions for use, but which may result from readily predictable human behavior.

7.2 Essentials of Safety and health. Paragraph 1. News

1.1.5 Design of machinery to facilitate its handling

The novelty is that the location changes and dangers unwanted by the lack of stability should be excluded when the manipulation is conducted in accordance with the instruction manual.

Ergonomics at 1.1.6 is developed in detail:

— Allowing for the variability of the operator's physical dimensions, strength and stamina.

— Providing enough space for movements of the parts of the operator's body.

— Avoiding a machine-determined work rate.

— Avoiding monitoring that requires lengthy concentration.

— Adapting the man/machinery interface to the foreseeable characteristics of the operators.

Operating positions.

The requirement mentioned only in paragraph 3 (...special hazards derived from the mobility of machines – 3.2.1 driving position) now is a general requirement for all machines.

- Points **1.2.1** and **1.2.7** are mixed like only one **1.2.1** and has expanded his reach. **Handing systems** should be designed and manufacturing for avoiding dangerous situations. Novelty is the requirement that in wireless control systems should occur automatically stop when not receiving the correct control signals.

- At the point **1.2.2** control devices, is particularly prevalent in the unintentional start indicating the need to implement commissioning organs in defined positions with adequate visualization of all risk areas.

- At the point **1.2.3** is signaled that if for safety reasons it is necessary for starting or stopping must be performed according to a specific sequence, there mechanisms to ensure that these operations are performed in the correct order.

- **1.2.4.2 Operational stop.**

  Directive 98/37/EC requires that when there will be a stop, the supply of organs must be stop.

  When for operational reasons, a stop is required that does not disrupt the energy supply to the actuators, is monitored and maintained stop conditions. In contrary of normal stops, at stops for operational functions not the supply to actuators is stop.

- **1.2.4.3 Emergency stop**

  In according to international hazards, `` emergency switch of devices´´ are going to be ``emergency stop devices´´.

  Stop function has to be available and operational permanently.

  Devices for emergency stops are used to improve security protective operations, not to replace them.

- **1.2.5 Selection of control or operating mode**

  If, for certain operations, the machinery must be able to operate with a guard displaced or removed and/or protective device disabled, the control or operating mode selector must simultaneously:

  — disable all other control or operating modes.

  — permit operation of hazardous functions only by control devices requiring sustained action.

— permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked sequences.

— prevent any operation of hazardous functions by voluntary or involuntary action on the machine's sensors.

- **1.2.6 Failure of the power supply**

  Has been added as a new feature that power supply failures should not change the machine parameters in an uncontrolled way when such change can lead to dangerous situations.

- **1.3.8.1 Moving transmission and 1.3.8.2 Moving parts involving in the process**

  Some of the changes of both sections are the result of the amendment to paragraph 1.4.2.2 in Annex I. Is a new need to decide if you need a receipt or not, what should be valued in the context of a risk assessment. In paragraph 1.3.8.1 may be necessary also interlocked guards, and in the case of paragraph 1.3.8.2 may be waived under certain circumstances.

- **1.3.9 Risk of uncontrolled movements.**

  When a part of the machinery has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, must be prevented or must be such that it does not present a hazard.

- **1.4.2.1 Fixed regards.**

  Has been added as a new feature that fixing systems must remain attached to the guards or to the machinery when the guards are removed.

- **1.4.2.2 Interlocking movable guards.**

  The distinction of movable guards A and B were disappeared and is replaced with the requirements for guards with interlocking device, with or without locking device.

- **1.5.8 Noise**

  The level of noise emission may be assessed with reference to comparative emission data for similar machinery.

- **1.5.9 Vibration**

  The level of vibration emission may be assessed with reference to comparative emission data for similar machinery.

- **1.5.10 Radiation**

  Have developed more detailed requirements, differentiating unwanted radiation and functional radiation, ionizing and non-ionizing.

- **1.5.15 Risk of slipping, tripping or falling.**

  Is added it is necessary, that machines must be equipped with fixed handles. Must be adapted to the user and ensure stability.

- **1.5.16 Lightning.**

  Machinery in need of protection against the effects of lightning while being used must be fitted with a system for conducting the resultant electrical charge to earth.

- **1.7.1 Information and warnings on the machinery.**

  Information and warnings on the machinery should preferably be provided in the form of readily understandable symbols or pictograms. Any written or verbal information and warnings must be expressed in an official Community language or languages.

  Also is a new, that information may be submitted in any official language understood by the operators.

- **1.7.1.1 Information and information devices.**

  The new is that display screens or other means of interactive communication between the operator and the machine must be easily understood and used.

- **1.7.3 Marking of machinery.**

  All machinery must be marked visibly, legibly and indelibly with the following minimum particulars:

  — the business name and full address of the manufacturer and, where applicable, his authorised representative.

  — designation of the machinery.

  — the CE Marking (see Annex III).

  — designation of series or type.

  — serial number, if any.

  — the year of construction, that is the year in which the manufacturing process is completed.

  —It is forbidden to pre-date or post-date the machinery when affixing the CE marking.

—Furthermore, machinery designed and constructed for use in a potentially explosive atmosphere must be marked accordingly.

➢ 1.7.4 Instructions.

— All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service.

The instructions accompanying the machinery must be either 'Original instructions' or a 'Translation of the original instructions', in which case the translation must be accompanied by the original instructions.

By way of exception, the maintenance instructions intended for use by specialized personnel mandated by the manufacturer or his authorised representative may be supplied in only one Community language which the specialized personnel understand.

—Extending the concept of machine in Article 1 at Directive means that these products must also possess an instruction manual completed as requirements of the directive:

- Security components
- Loading means
- Chains, robes and webbing
- Removable mechanical transmission devices

Besides, requirements about instructions content have these precisions and have been amplify with this information:

- The EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature.
- Warnings concerning ways in which the machinery must not be used that experience has shown might occur.
- Information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;
- Instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided.
- Information on airborne noise emissions.

7.3 Supplementary essential requirements safety and health for some categories of machinery. Paragraph 2. News

- Requirements of section **2.1** is applied to machinery for food and also machines for cosmetics and pharmaceuticals.

- **2.2 Portable hand- held and/or hand- guide machinery.**

  2.2.1 Generalities.

  The handles of portable machinery must be designed and constructed in such a way as to make starting and stopping straightforward.

  2.2.1.1 Instructions.

  - Should indicate the value of the vibration to the system is exposed to hand arm
  - The indicated values should be accompanied by the corresponding uncertainty
  - Laying down conditions for the measurement methods

  2.2.2 Portable fixing and other impact machinery.

  This point is new and inside this kind of machines are warhead machines introduced in the field of application of Directive.

- **2.3 Machinery for working wood and material with similar physical characteristics.**

  Projection risk refers not only to the parts but also parts of them.

7.4 Supplementary essential to neutralize safety and health hazards due to mobility of the machines. Paragraph 3. News

- **Seating.**

  Is required to implement a system of retention also on machines equipped with FOPS (non falling objects).

  Shouldn't implement a retention system if this one improve risk.

- **Control systems**

If necessary, steps must be taken to prevent unauthorized use of controls.

In the case of remote controls, each control unit must clearly identify the machinery to be controlled from that unit.

The remote control system must be designed and constructed in such a way as to affect only:

— the machinery in question,

— the functions in question.

Remote controlled machinery must be designed and constructed in such a way that it will respond only to signals from the intended control units.

- **3.3.1 Control devices**

The sixth paragraph of section 1.2.2 about audible and visual warning signals will be applied only in the case of reverse gear.

- **3.3.3 Travelling function**

Remote-controlled machinery must be equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations:

— if the driver loses control,

— if it receives a stop signal,

— if a fault is detected in a safety-related part of the system,

— if no validation signal is detected within a specified time.

- **3.4.3 Roll- over and tip- over**

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery must be fitted with an appropriate protective structure, unless this increases the risk.

- **3.4.4 Falling objects**

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk due to falling objects or material, the machinery must be designed and constructed in such a way as to take account of this risk and fitted, if its size allows, with an appropriate protective structure.

- **3.4.7 Transmission of power between self- propelled machinery (or tractor) and recipient machinery.**

  It must be possible to open this guard for access to the removable transmission device. Once it is in place, there must be enough room to prevent the drive shaft damaging the guard when the machinery (or the tractor) is moving.

- **3.5.3 Emission of hazardous substances.**

  The operator must be protected against the risk of exposure to such hazardous emissions.

- **3.6.1 Sings, signals and warnings.**

  Where necessary, there must be an appropriate connection between a trailer and the machinery for the operation of signals.

- **3.6.3.1 Vibrations.**

  The instructions must give the following information concerning vibrations transmitted by the machinery to the hand-arm system or to the whole body:

  — the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s^2. Where this value does not exceed 2,5 m/s^2, this must be mentioned,

  — the highest root mean square value of weighted acceleration to which the whole body is subjected, if it exceeds 0,5 m/s^2. Where this value does not exceed 0,5 m/s^2, this must be mentioned,

  — the uncertainty of measurement.

7.5 Supplementary essential requirements of safety and health to neutralize the dangers of lifting operations. Paragraph 4. News

- 4.1.2.8 Machinery serving fixing landing.

  - **4.1.2.8.1 Movements of the carrier.**

    The movement of the carrier of machinery serving fixed landings must be rigidly guided to and at the landings. Scissor systems are also regarded as rigid guidance.

  - **4.1.2.8.2 Access to the carrier.**

Where persons have access to the carrier, the machinery must be designed and constructed in such a way as to ensure that the carrier remains stationary during access, in particular while it is being loaded or unloaded.

The machinery must be designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.

- **4.1.2.8.3 Risk due to contact with the moving carrier.**

Where necessary in order to fulfill the requirement expressed in the second paragraph of section 4.1.2.7, the travel zone must be rendered inaccessible during normal operation.

When, during inspection or maintenance, there is a risk that persons situated under or above the carrier may be crushed between the carrier and any fixed parts, sufficient free space must be provided either by means of physical refuges or by means of mechanical devices blocking the movement of the carrier.

- **4.1.2.8.4 Risk due to the load falling off the carrier.**

Where there is a risk due to the load falling off the carrier, the machinery must be designed and constructed in such a way as to prevent this risk.

- **4.1.2.8.5 Landings.**

Risks due to contact of persons at landings with the moving carrier or other moving parts must be prevented.

Where there is a risk due to persons falling into the travel zone when the carrier is not present at the landings, guards must be fitted in order to prevent this risk. Such guards must not open in the direction of the travel zone. They must be fitted with an interlocking device controlled by the position of the carrier that prevents:

— hazardous movements of the carrier until the guards are closed and locked,

— hazardous opening of a guard until the carrier has stopped at the corresponding landing.

- **4.1.3 Fitness for purpose.**

The static and dynamic tests referred to in section 4.1.2.3 must be performed on all lifting machinery ready to be put into service.

- **4.4.1 Lifting accessories.**

  In the instruction should also indicate how new the static test coefficient is used.

- **4.4.2 Lifting machinery.**

  In instructions should also indicate where appropriate, a report that details the static and dynamic tests conducted by or for the manufacturer or his authorized represented.

7.6 Additional essential requirements of safety and health to neutralize the dangers of lifting operations. Paragraph 6. News

- **6.1.1 Mechanical strength.**

  The carrier, including any trapdoors, must be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load.

  If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.

- **6.1.2 Loading control for machinery moved by power other than human strength**

  The requirements of section 4.2.2 apply regardless of the maximum working load and overturning moment, unless the manufacturer can demonstrate that there is no risk of overloading or overturning.

- **6.2 Control devices.**

  The control devices for these movements must be of the hold-to-run type except where the carrier itself Is completely enclosed.

- **6.3.2 Risk of persons falling from the carrier.**

  When the carrier is designed as a work station, provision must be made to ensure stability and to prevent hazardous movements.

  Any trapdoor in floors or ceilings or side doors must be designed and constructed in such a way as to prevent inadvertent opening and must open in a direction that obviates any risk of falling, should they open unexpectedly.

- **6.3.3 Risk due to objects falling on the carrier.**

  Where there is a risk of objects falling on the carrier and endangering persons, the carrier must be equipped with a protective roof.

- **6.4 Machinery serving fixed landing. NEW POINT. For cover the new Directive about lifts and lower has been created this point.**
  - **6.4.1**

    The carrier must be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfill this requirement, the carrier itself must be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless the doors are closed. The doors must remain closed if the carrier stops between landings where there is a risk of falling from the carrier.

    The machinery must be designed, constructed and, where necessary, equipped with devices in such a way as to prevent uncontrolled upward or downward movement of the carrier. These devices must be able to stop the carrier at its maximum working load and at the foreseeable maximum speed.

    The stopping action must not cause deceleration harmful to the occupants, whatever the load conditions.

  - **6.4.2 Controls at landings**

    Controls, other than those for emergency use, at landings must not initiate movements of the carrier when:

    — the control devices in the carrier are being operated,

    — the carrier is not at a landing.

  - **6.4.3 Access to the carrier**.

    The guards at the landings and on the carrier must be designed and constructed in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons to be lifted.

- **6.5 Markings.**

  The carrier must bear the information necessary to ensure safety including:

  — the number of persons permitted on the carrier,

  — the maximum working load.

8. Annex IV

Categories of machinery to which one of the procedures referred to in Article 12(3) and (4) must be applied:

1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:

1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the work piece or with a demountable power feed;

1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage.

1.3 sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the work pieces, with manual loading and/or unloading.

1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.

2. Hand-fed surface planning machinery for woodworking.

3. Thicknesses for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.

4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:

4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the work piece;

4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.

5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.

6. Hand-fed tenoning machinery with several tool holders for woodworking.

7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.

8. Portable chainsaws for woodworking.

9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.

10. Injection or compression plastics-moulding machinery with manual loading or unloading.

11. Injection or compression rubber-moulding machinery with manual loading or unloading.

12. Machinery for underground working of the following types:

12.1. locomotives and brake-vans;

12.2. hydraulic-powered roof supports.

13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.

14. Removable mechanical transmission devices including their guards.

15. Guards for removable mechanical transmission devices.

16. Vehicle servicing lifts.

17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three meters.

18. Portable cartridge-operated fixing and other impact machinery.

19. Protective devices designed to detect the presence of persons.

20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11.

21. Logic units to ensure safety functions.

22. Roll-over protective structures (ROPS).

23. Falling-object protective structures (FOPS).

9. Conformity assessment procedures

The assessment conformity procedure for products not listed in the Annex IV of the Directive (the so-called list of dangerous machines) varies not only by regard to products not listed in Annex.

It means that everything is similar for products that manufacturers who marketing that products of the Directive from them responsibility.

However, there is now the formally obligation for these products a manufacturing control, internal by the manufacturer in accordance with the Annex VIII to Directive.

The only exception regarding the responsibility of the manufacturer when marketing their products is, in the case of security components, in so-called logical drives for safety functions, which are also included in the Annex IV of Directive.

9.1 Annex IV procedure

Depending on whether the product in question is or not an harmonized EN hazard under the umbrella of the policy in the future will be able to choose up procedures over conformity assessment.

- OPTION 1: Internal manufacturing control by the manufacturer in according to annex VIII of Directive, it means, manufacturers own responsibility.
- OPTION 2: Total quality assurance by the manufacturer in accordance with the Annex X of Directive.
- OPTION 3: Test CE in according to annex IX of Directive.

In the exceptional case of for the product, won't exist an harmonized EC hazard, option 1 is not valid.

On contrary, in the case of products inside annex IV disappears in the future the possibility of present or test documentation from a designated entity.

CONFORMITY ASSESSMENTS PROCEDURE	
DIRECTIVE 98/37/EC ARTICLE 8	**DIRECTIVE 2006/42/EC ARTICLE 12**
NOT INCLUDED MACHINE IN ANNEX IV	
Realize technical file of annex V (based on A module)	Internal control of manufacturing annex VIII (based on A module)
MACHINE INCLUDED IN ANNEX IV MANUFACTURED IN ACCORDANCE WITH HARMONIZED HAZARDS	
• Receive and retain the technical file • Review of adequacy of the technical file • Type examination EC according to annex IV (based on B module)	• Internal production control annex VIII (based on A module) • EC type examination according to annex IX + internal control point · annex VIII (based on A and B module) • Total quality assurance according to annex X (based on H module)
NOT INCLUDE MACHINE IN ANNEX IV NOT MADE WITH HARMONIZED HAZARDS	
• EC type examination according to annex IV (based on B module)	• EC type examination according to annex IX +internal control point 3 annex VIII (based on A and B module) • Total quality assurance according to annex X (based on H module)

TABLE 3. Conformity assessments procedure.

9.2 Full quality assurance in accordance with Annex X

This new option for products of Annex IV should make a significant simplification for manufacturers, particularly of unique, special machines and special orders of customer specific, as from an economic point of view in relation with the time of market.

Annex X describes essentially a system of total quality assurance, in the sense of the ISO 9000 series of standards and following, but there are two differences.

The first difference is the greater weight of the design and specification of products in the relevant processes of quality assurance. In this case, it is not only the quality of manufacturing but also the quality of the design from the point of view of technical safety.

The second difference is the quality assurance system test from a assigned entity.

9.3 Internal production control in accordance with Annex VII

This Annex describes the procedure by which the manufacturer or his authorized representative, who carries out the obligations laid down in points 2 and 3, ensures and declares that the machinery concerned satisfies the relevant requirements of Directive.

INTERNAL PRODUCTION CONTROL IN ACCORDING WITH ANNEX VII	
DIRECTIVE 98/37/EC ARTICLE 8	DIRECTIVE 2006/42/EC ARTICLE 12
ALL MACHINES MUST HAVE A TECHNICAL FILE	
NON INCLUDED MACHINES IN ANNEX IV • Construction technical file according to annex V INCLUDED MACHINES IN ANNEX IV • Construction technical file according to annex VI	FOR ALL MACHINES • Technical file in according to annex VII, A paragraph (paragraph B technical documentation of partly completed machines) NEWS • Machine worked description • Risk evaluation documentation • Indicate the residual risk • Standards and technical specifications indicating the RESS covered by the rules • Declaration of conformity

TABLE 4. Internal production control in according with annex VII of Directive 2006/42/EC.

9.4 EC type-examination in accordance with Annex IX

- Moreover, the applicant shall place at the disposal of the notified body a sample of the type.
- Carry out or have carried out appropriate inspections, measurements and tests to ascertain whether the solutions adopted satisfy the essential health and safety requirements of this Directive, where the standards referred to in Article 7(2) were not applied.
- The manufacturer and the notified body shall retain a copy of this certificate, the technical file and all relevant documents for a period of 15 years from the date of issue of the certificate.
- The applicant shall inform the notified body which retains the technical file relating to the EC type-examination certificate of all modifications to the approved type.
- Validity of the EC type-examination certificate is for 5 years.

- The notified body shall withdraw certificates which are no longer valid.
- In the event that the validity of the EC-type examination certificate is not renewed, the manufacturer shall cease the placing on the market of the machinery concerned.
- The manufacturer shall request from the notified body the review of the validity of the EC type-examination certificate every five years.

10. Frequently asked questions regarding the transition from the Machinery Directive (98/37/CE) to the revised new directive (2006/44/CE)

1. QUESTION:

Is there a transition period for application of Directive 2006/42/EC?

ANSWER:

In general, there is no transition period, in the sense of a period during which both the current Machinery Directive and the new Machinery Directive are applicable (with one exception: there is a transition period until 29th June 2011 for the particular case of portable cartridge- operated fixing another impact machinery).

However there is a period of adaptation, since the provisions of the Directive 2006/42/EC become applicable on 29th December 2009. During this period, all of the stakeholders concerned will be able to take the necessary steps to ensure a smooth transition from the current Directive to the new Directive.

2. QUESTION:

Can manufacturers anticipate application of the new Machinery Directive?

ANSWER:

Yes and no. Manufacturers can and should anticipate application of Directive 2006/42/EC from a practical and technical point of view, however, from a formal, legal point of view, the Directive cannot be applied before 29th December 2009:

- From the practical and technical point of view, manufacturers are encouraged to review their products without delay and adapt them as necessary to take account of the requirements of the new Directive. While machinery placed on the market before 29th December 2009 must continue to comply with Directive 98/37/EC , it can be assumed that a product that complies with the essential requirements of the new Machinery Directive continues to comply with the current Directive.

- From the formal, legal point of view, machinery can only be placed on the market with reference to Directive 2006/42/EC as from 29th December 2009.

3. QUESTION:

When shall a manufacturer establish an EC Declaration of conformity according to Directive 2006/42/EC?

ANSWER:

A manufacturer shat establish an EC Declaration of conformity according to Directive 2006/42/EC for products first placed on the market as from 29th December 2009.

In cases where the manufacturer cannot be certain on what date individual products will be first placed on the market, providing the products concerned comply with both the current and the new Directives, he may establish an EC Declaration of conformity referring to both Directive 98/37/EC and Directive 2006/42/EC. The reference to Directive 98/37/EC should be removed from the EC Declaration of conformity after the 29th December 2009.

4. QUESTION:

Can the current harmonized standards be used to comply with Directive 2006/42/EC?

ANSWER:

Since there have been some modifications to the essential health and safety requirements set out in Annex I, it cannot be assumed that the current harmonized standards comply fully with Directive 2006/42/EC.

The European commission is issuing a mandate to CEN and Cenclec to develop the necessary new standards and ensure that the current standards are checked against Directive 2006/42/EC and adapted as necessary. Furthermore, all harmonized standards must include a reference to the new Directive. The Commission intends to publish a list of harmonized standards supporting Directive 2006/42/EC before the Directive becomes applicable.

5. QUESTION:

When will manufacturers be able to use the new full quality assurance procedure for Annex IV machinery?

ANSWER:

The Member States will first have to assess, appoint and notify Notified Bodies for the new full quality assurance procedure set out in Annex X of the new Directive. This can be done as soon as Directive 2006/42/EC has been transposed into national law.

As soon as Bodies have been notified for this procedure, they will be able to carry out the necessary audits and inspections and issue approvals of manufacturers full quality assurance systems. However, products cannot be placed on the market on the basis of such approvals until Directive 2006/42/EC becomes applicable on 29th December 2009.

6. QUESTION:

Will the existing Notified Bodies be able to carry out EC type- examinations according to Directive 2006/42/EC?

ANSWER:

Bodies that are notified to carry out EC type- examinations under Directive 98/37/EC will be able to continue to carry out EC type- examinations under Directive 2006/42/EC, providing their notification covers the product categories concerned.

For product categories included in Annex IV of Directive 2006/42/EC that are not listed in Annex IV of Directive 98/37/EC, the Member States will have to notify new Bodies or extend the scope of the notification of existing ones.

7. QUESTION:

Will EC type- examination certificates established according to Directive98/37/EC remain valid for Directive 2006/42/EC??

ANSWER:

Since there have been some modifications to the essential health and safety requirements set out in Annex I, it cannot be assumed that EC type- examination certificates issued according to Directive 98/37/EC remain valid for Directive 2006/42EC. Furthermore, such certificates must be updated to refer to Directive 2006/42/EC.

Notified Bodies will thus have to review existing EC type- examination certificates to ensure that they remain valid in light of the requirements of the new Directive and update them to refer to Directive 2006/42/EC. Manufactures are encouraged to request this review without delay in order to avoid a bottleneck in the months preceding December 2009.

Since Directive 2006/42/EC requires EC type- examination certificates to be reviewed every 5 years (see Annex IX, section 9.3), the 5 year period for existing certificates can be counted from the date on which they have been updated according to Directive 2006/42/EC.

8. QUESTION:

What will happen to products certified according to one of the procedures set out in Article 8 (2,c) of Directive 98/37/EC (Receipt of technical file or Certificate of adequacy to harmonized standards)?

ANSWER:

The procedures set out in Article 8 (2,C) of Directive 98/37/EC will no longer exist under Directive 2006/42/EC. As from 29th December 2009, manufacturers of products placed on the market on the basis of these procedures will therefore have to apply one of the procedures set out in Article 12(3) and (4) of Directive 2006/42/EC.

For products manufactured in accordance with harmonized standards that cover all the relevant health and safety requirements, the manufacturer will be able to certify the conformity of the product himself according to the procedure set out in Article 12 (3, A) of the Directive.

CHAPTER 3. SUBSTANCIAL CHANGES IN MACHINES

At the new Directive 2006/42/EC, these concepts remain unchanged and, at this time without clarification. Consequently, also raises the question of when a substantial change in a machine is coming, when conditions of the policy are applied and when not.

In this sense it is recommended to apply a decision tree, as illustrated in the flowchart shown next (based on an interpretive guide the administration of Federal Government on this issue).

This does not mean in any way that in these cases is to tolerate a level of security on the machine substantially lower, rather what has to be considered is that the requirements of the new Machinery Directive cannot be met fully in practice when modifications will change machines.

Anyway should apply the basic rules of safe operation of the same, it means, should apply the requirements specified in Annex I of Directive.

In according with the last scheme, it should indicate:

- ✓ The analysis respect flow char should be a team work and it must be documented.
- ✓ Modifications of security systems must not be considered substantial modifications. Only at the reduction of security systems (dismantling) could constitute a substantial modification.
- ✓ In expert circles is discussed very intensively if the correction by simple safeguards can also be achieved by incorporating other safeguards, such as Interlocked guards or guards contactless. This question can be answer with an affirmation when the protection versus risk is dominated as well or better, and interventions of control elements are surface.

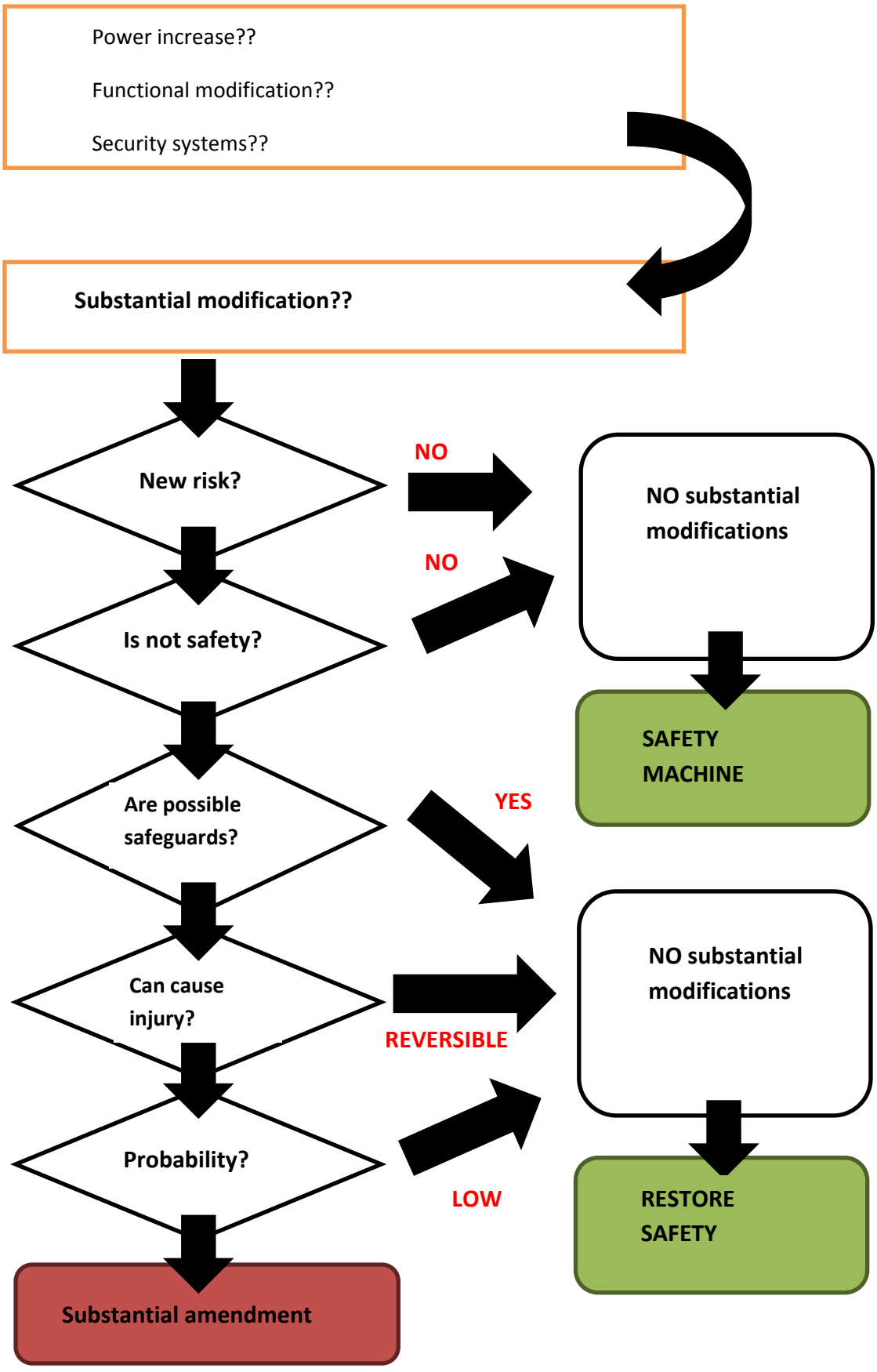

Power increase??
Functional modification??
Security systems??
Substantial modification??
New risk?
NO
NO substantial modifications
NO
Is not safety?
SAFETY MACHINE
Are possible safeguards?
YES
Can cause injury?
REVERSIBLE
NO substantial modifications
Probability?
LOW
RESTORE SAFETY
Substantial amendment

FIGURE 15. Flow chart about make changes, substantial changes or restore safety in machines at Directive 2006/42/EC.

CHAPTER 4. MACHINERY INSTALATION

Sets of machinery and partly completed machinery have not undergone any change in the scope of application of the new policy and therefore no practical issues related to them.

This theme requires a special consideration, particularly under three points of view:

1. General responsibility

Who has overall responsibility when a machine installation does not have a single source, which can also mean that machines (regardless of whether they are completed or partly completed machinery) have been provided by third-party manufacturers (including construction machinery itself).

In this case is necessary (in the best of the cases in advance) the appointment of a general contractor (a systems integrator) who respond to the Directive under the total installation.

In the case of the general responsibility question don't be regulated, the responsible by the point of view of the Directive will be the operator of machine.

2. Installation formed by new and old machines

In relation to paragraph 1, may often a set of new grouping machines that are not compound only by new machines. Is more likely to be machinery or partly completed machinery with more manufacturing years old.

In this case, the question arises to value the fact that one of these machines present a state of a previous technological security systems towards meeting the requirements of the directive on machines.

This question raises the same dilemma that when a machine has a substantial modification and when not.

Usually applies the principle that the machines conform to EC previous model years maintaining the state purchased. It means that machines in a past date were safe in the sense of the requirements and conditions of the policy effect at that time remain safe.

Maintaining acquired condition also applies to the classic old machines, it means machines prior to the time of the policy, so generally these old machines can be incorporated as such in new facilities.

When the integration is composed with old machines prior to 98/37/EC directive, machinery subsequent to this and other more modern conform to the new policy, the general contractor, which preferably should be designated previously certified EC compliant of integration. If necessary, the conditions or requirements of EU directives which cannot be met in the old machines should be highlighted in a continuation sheet attached to the EC declaration of conformity.

3. Is the integration only one machine?

A third issue which is frequently arise in connection with the machinery installation is when the group of machines is a machine installation and when not.

According to this principle, there isn't a set of machines in the sense of the directive that consists of machines capable of operating independently (or partial installations capable of operating independently) that are connected from the functional point of view and control, but it does not constitute a unit from the point of view of safety in the sense indicated above. This happens, for example, when the transition points don't happens a risk, between machines because of their grouping.

Chain connected machines can still be considered separate from the standpoint of safety. In this case, the policy states that security measures are taken only in the individual machine.

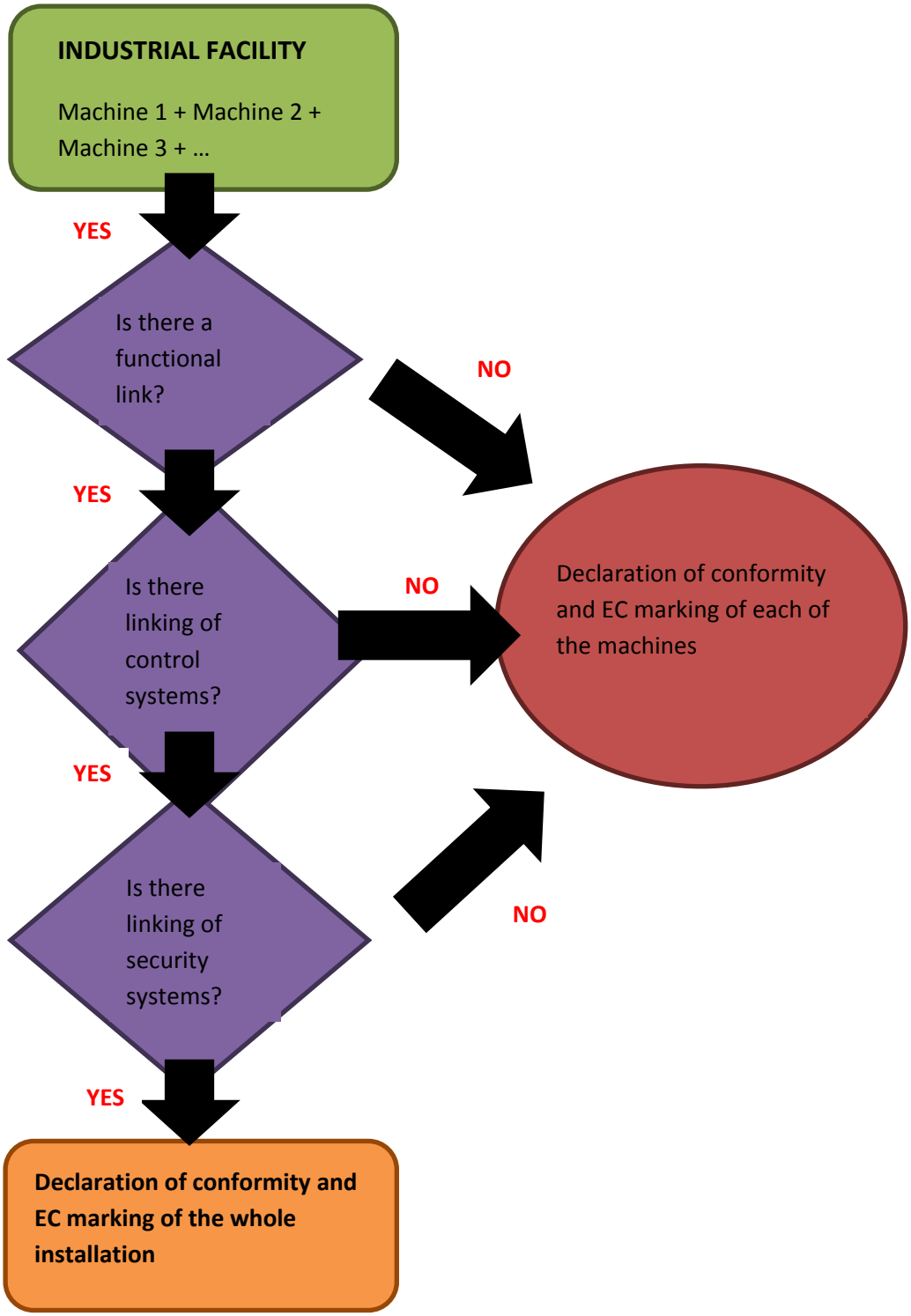

INDUSTRIAL FACILITY
Machine 1 + Machine 2 + Machine 3 + …
YES
Is there a functional link?
NO
YES
Is there linking of control systems?
NO
Declaration of conformity and EC marking of each of the machines
YES
Is there linking of security systems?
NO
YES
Declaration of conformity and EC marking of the whole installation

FIGURE 16. Flow chart describing how a machine is composed.

CHAPTER 5. OTHER APPICALY DIRECTIVES

New Machinery Directive has added through Annex I security objectives of Low Voltage Directive so that in the future could be deleted list of directive 73/23/EEC on the two statements on product conformity .

Manufacturer has to determine which directives apply to their machines. Therefore, should check if the machines:

1. Are inside the application scope of the Machines Directive.
2. Are within the scope of application of the other directives in accordance with the requirements of Article 4 (building products, medical products, toys or elevators).
3. Are inside the application scope of the new Directive which is applied at the same time for risk or specific assemblies (pressure equipment, electromagnetic compatibility and noise emissions).

Between directives that cover **specific risks** are:

- Directive 94/9/EC (Directive Atex)
- Directive 2000/14/EC (noise emission in the environment by equipment for use outdoors)
- Directive 2004/18/EC (Directive about electromagnetic compatibility)

In contrast, there are other directives which product groups in more detail. Is also possible that in the case of a product which hasn't got risk, or is so low that is appropriate to have a security level about this risk. In those cases we would also apply Article 3. Risk would be referred more specifically.

Examples of those Directives:

- Directive 93/42/EEC (Medical products Directive)
- Directive 88/378/EEC (Toys Directive)
- Directive 95/16/EC (Lifts Directive)
- Directive 2000/9/EC (relative to the people transport by cable)
- Directive 97/23/EC (Pressure Equipment Directive)

CHAPTER 6. EN HARMONIZED STANDARDS

1. A new approach

The important role that standardization reserves in the EU comes from Europe White Paper on completing the internal market, approved by the European Council in June 1985, which provides at paragraphs 65 and 68 resort to a `` new approach´´ to technical harmonization and standardization. This new approach involves a deeper integration of European standardization in the following aspects.

a) Policies that are developed under the umbrella of this `` new approach'' cover very large sets of products with different risk levels. Technical specifications contained in them are limited to include aspects of general safety and health with these products should be placed on the market in order to benefit from their free circulation in the EU.
b) Standards organizations of the member states are in charge of preparing the technical specifications necessary for the manufacture and marketing of products according to the basic requirements of health and safety guidelines established by taking into account, of course, the current of technology.
c) These are the so-called technical specifications **harmonized standards**, which are not compulsory and therefore maintain their voluntary character, it means them will never be transformed into regulations and therefore will maintain complete independence. Your role will be a preferential solution to meet the basic requirements of safety and health policies and therefore a refutable presumption of conformity, however, manufacturers who take them into account when making their products, will benefit from a faster market access.
d) For the certification of a product, conformity to harmonized standards leads to the possibility of a declaration of conformity by the manufacturer, in the case not followed these rules, or in the event that they do not exist, the direct application of the basic requirements of health and safety directives implicate a certification by a notified body.
e) Following these harmonized standards and national standards are recognized as temporarily presumption of conformity with the essential requirements of safety and health policies is ensured through a standing committee composed of representatives of the member states. This Standing Committee, will attend as well to the EU Commission for administrations of member states to provide procedural safeguards designed to challenge the conformity of a product, the validity of a certificate or the quality of the standard.

2. Concept

Are those rules adopted by consensus by the Commission which, the design and manufacture of a product as well as the adjustments are made in ensuring safety through compliance with safety specifications of the product or team in question . The fulfillment of a harmonized safety standard specifies give presumption of conformity because this standard has been agreed by the member countries of the EU.

Definition of the harmonized standard according to Directive 2006/46/EC Article 2-I:

> 'harmonized standard' means a non-binding technical specification adopted by a standardization body, namely the European Committee for Standardization (CEN), the European Committee for Electro technical Standardization (CENELEC) or the European Telecommunications Standards Institute (ETSI), on the basis of a remit issued by the Commission in accordance with the procedures laid down in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (1).

FIGURE 17. Important information about Directive 2006/42/EC.

3. Classification of European harmonized standards

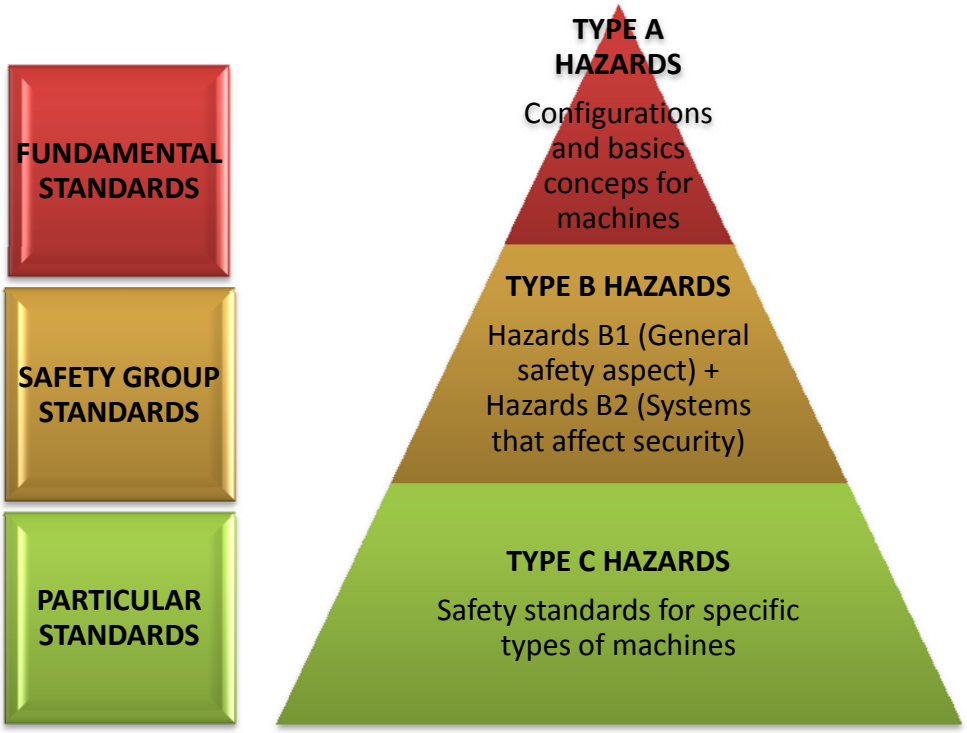


FIGURE 18. Classification of hazards in horizontal and vertical.

a) **Horizontal standards** relating to the technological, metodological and terminology related to machine safety and can be applied to any machine or set of important machines. Inside this category are the rules relating to safety devices or components that can be widely used in the design of the machines.
Under the rules are the so-called rules of types A and B of detailing later.

b) **Vertical** standards that are the horizontal complementary rules from the moment that only particular aspects of safety are include refer to a machine or set of machines. These standards should be used in conjunction with horizontal rules.
Inside this category are the so-called standard Type C standards detailed below.

European standards developed by the Machinery Directive are classified into four types:

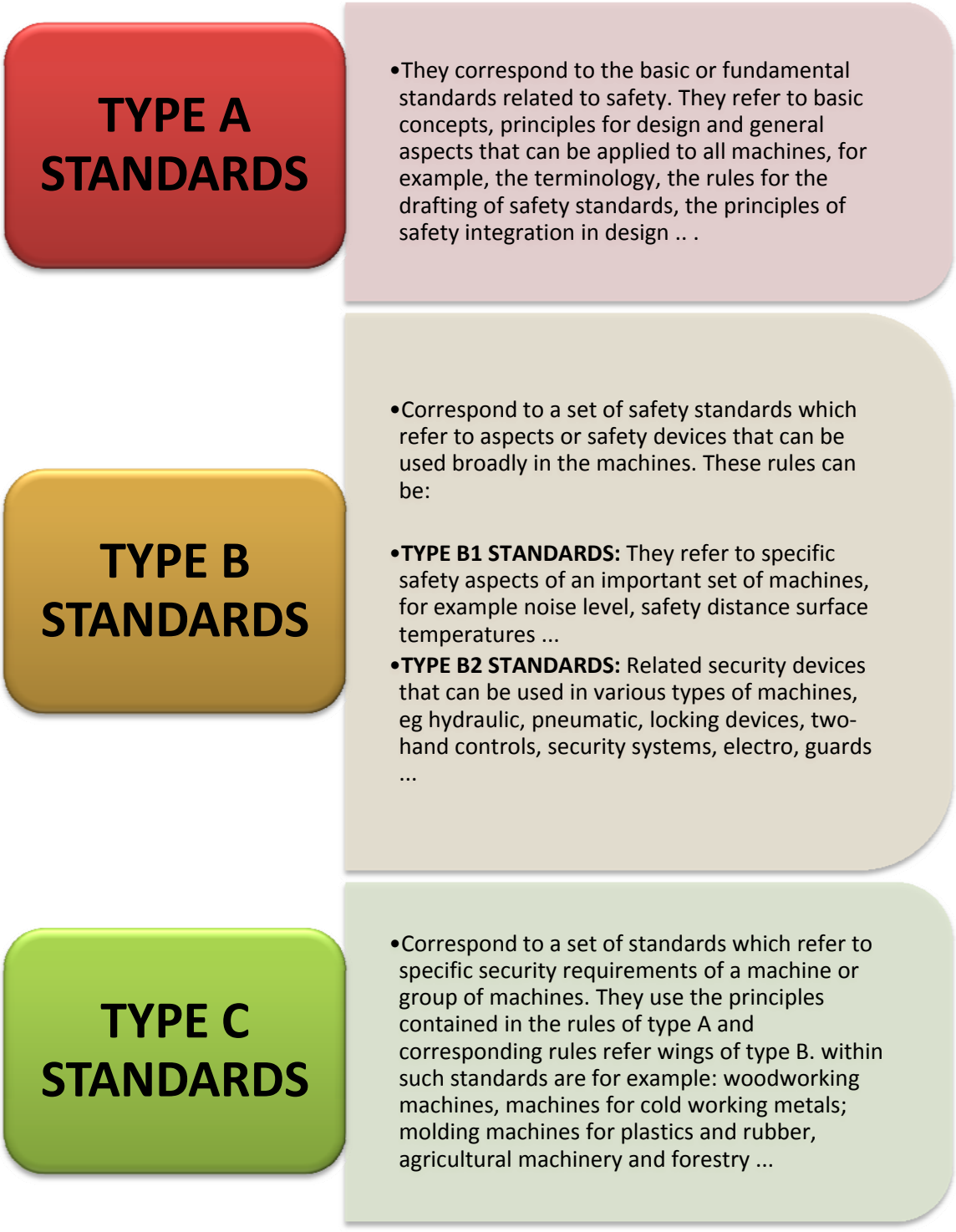


FIGURE 19. Classification of standards between A, B or C.

A and B standards can be used at machines design in defaulf of C standards.

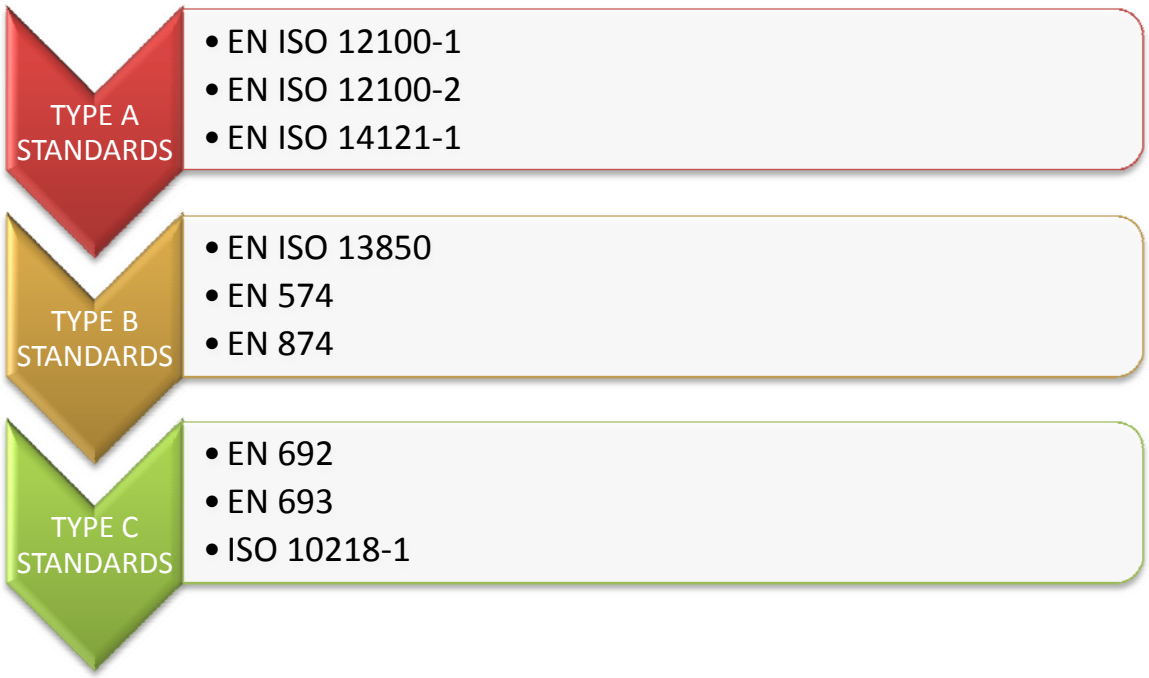


FIGURE 20. Classification between standars of different hazards.

4. List of EN standards in type A and B into force

EN ISO 12100	A	Safety of machinery - General principles for design - Risk assessment and risk reduction
EN 574	B	Safety of machinery - Two-hand control devices - Functional aspects - principles for design
EN ISO 13850	B	Safety of machinery - Emergency stop - Principles for design
EN 62061	B	Safety of machinery - Functional safety of safety-related electrical, electronic and programmable electronic control systems
EN ISO 13849-1	B	Safety of machinery - Safety-related parts of control systems - Part 1: general principles for design
EN 349	B	Safety of machinery - Minimum gaps to avoid crushing of parts of the human body
EN ISO 13857	B	Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs
EN 60204-1	B	Safety of machinery - Electrical equipment of machines - Part 1: general requirements
EN ISO 13855	B	Safety of machinery - Positioning of safeguards in respect of approach speeds of parts of the human body
EN 1088	B	Safety of machinery - Interlocking devices associated with guards - Principles for design and selection
EN 61496-1	B	Safety of machinery - Electro-sensitive protective equipment. Part 1: General requirements and tests
EN 60947-5-5	B	Low-voltage switchgear and control gear - Part 5-5: Control circuit devices and switching elements - Electrical emergency stop device with mechanical latching function
EN 842	B	Visual danger signals - General requirements, design and testing
EN 1037	B	Prevention of unexpected start-up
EN 953	B	General requirements for the design and construction of fixed and movable guards
EN 201	C	Plastics and rubber machines - Injection moulding machines - Safety requirements
EN 692	C	Machine Tools - Mechanical presses - Safety
EN 693	C	Machine Tools - Safety - Hydraulic presses
EN 289	C	Plastics and rubber machines – Presses - Safety requirements
EN 422	C	Plastics and rubber machines - Blow moulding machines - Safety requirements
EN ISO 10218-1	C	Robots and robotic devices - Safety requirements for industrial robots - Part 1: Robots
EN 415-3	C	Safety of packaging machines - Part 3: Form, fill and seal machines
EN 619	C	Continuous handling equipment and systems - Safety and EMC requirements for equipment for mechanical handling of unit loads
EN 620	C	Continuous handling equipment and systems - Safety and EMC requirements for fixed belt conveyors for bulk materials

FIGURE 21. List of Different standards into force between A and B.

CHAPTER 7. RISK ANALYSIS EN 14121-1

ALL MANUFACTURER SHOULD TO REALIZE AN RISK EVALUATION TO KNOW WHAT STANDARDS HAVE TO BE APPLY AND IN WHAT MEASURE

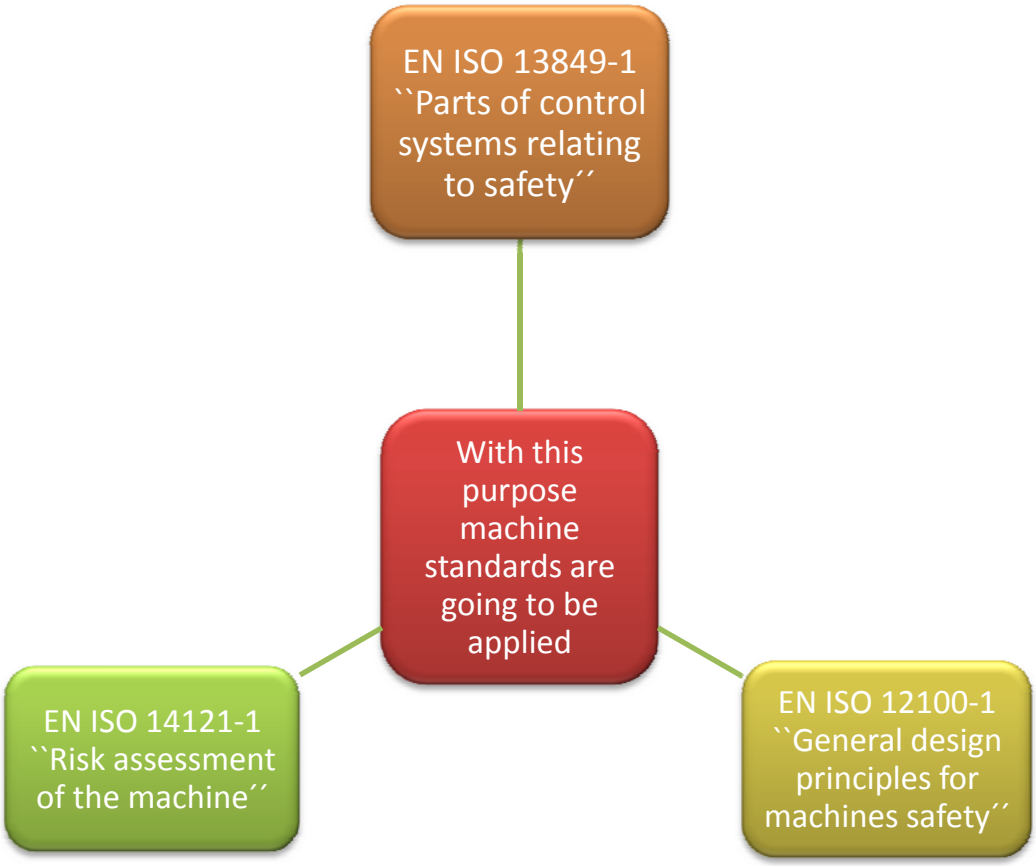


FIGURE 22. Different standards to measure risk.

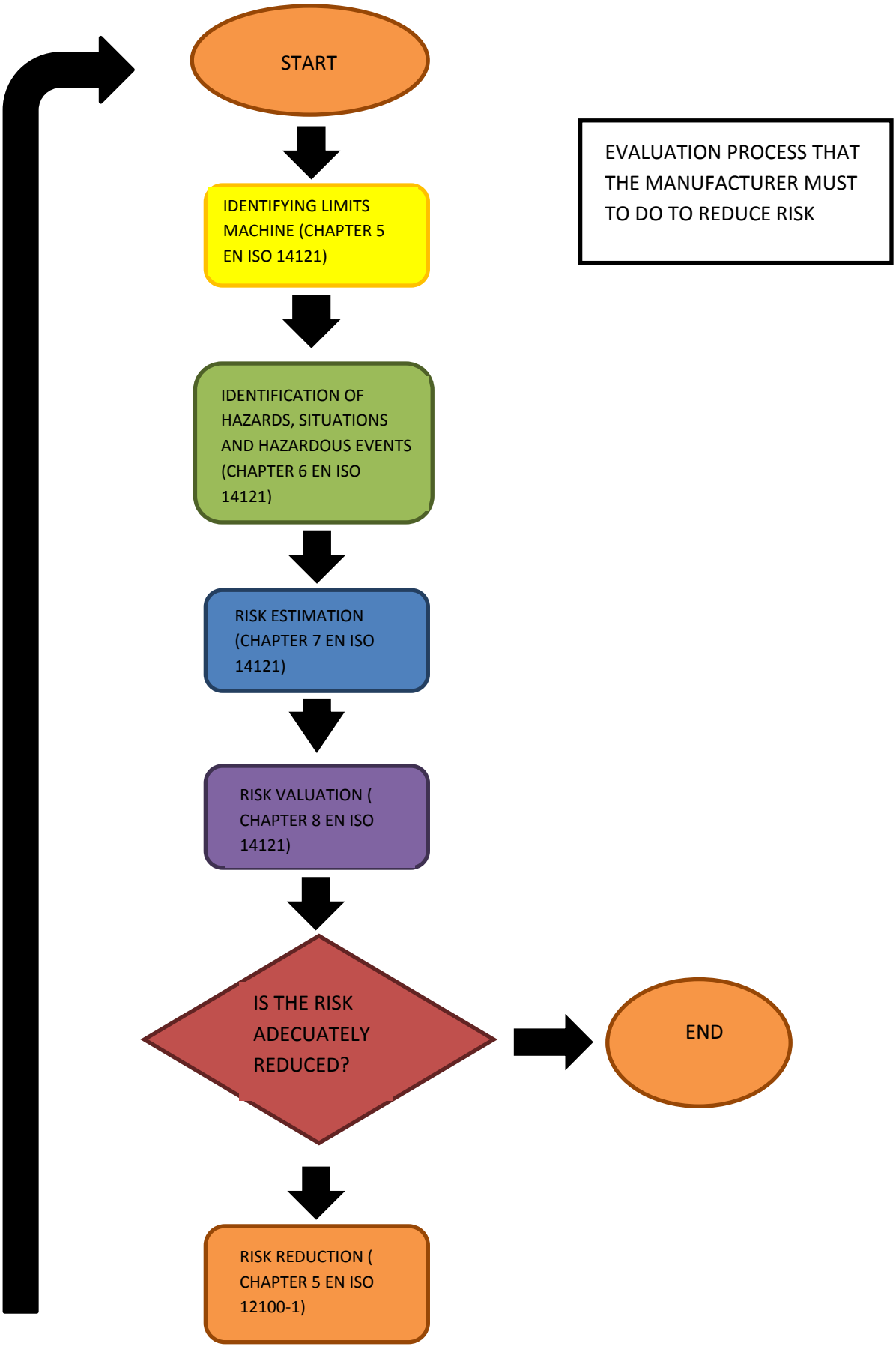


FIGURE 23. Evaluation process that the manufacturer must to comply to reduce risk.

1. Machine limits definition. Chapter 5 of the standard

EXTRACTS OF EN ISO 14121-1

The risk assessment begins with the determination of the limits of the machine, taking into account all stages of the life cycle of the machine. This means that you should identify the characteristics and performance of the machine or series of machines included in an integrated process, as well as those of the people involved, the environment and products, in terms of limits of the machine as described in the following sections:

- Limits of Use
- Limitations in space
- Limits on time
- Other limits (environmental conservation ..)

2. Identifying dangers, situations and danger events. Chapter 6 of the standard

EXTRACTS OF EN ISO 14121-1

After determination of the limits of the machine, the essential step in any risk assessment of a machine is the systematic identification of all hazards, hazardous situations and hazardous events that are reasonably foreseeable, during all phases of the life cycle the machine, it means:

a) Transport, assembly and installation;

b) Commissioning;

c) Use;

d) Decommissioning, dismantling and removal;

Should also consider all the tasks that can be done during the active life of the machine:

- Adjustment;
- Tests / trials;
- Learning / programming;
- Change process or tools;
- Implementation;
- All modes of operation;
- Feeding the Machine;
- Stop the machine;

- Stopping the machine in an emergency;
- After restore of a jam;
- Restarting after an unscheduled stop;
- Search / detection avveria (operator intervention);
- Cleaning and maintenance;
- Preventive maintenance;
- Corrective maintenance.

3. Risk estimation. Chapter 7 of the standard

EXTRACTS OF EN ISO 14121-1

After identification of hazards should perform risk estimation for each dangerous situation, determining elements of risk. When determining these elements is necessary to consider the items listed in the paragraph.

3.1 Risk elements

The risk associated with a particular hazard situation depends on the following:

a) Its severity;

b) The probability of occurrence of such damage, which is a function of:

- exposure of individuals to the danger;
- the occurrence of a hazardous event;
- technical and human possibilities to avoid or limit the damage.

3.2 Aspects to consider during the risk estimation

- People exposed
- Type, frequency and duration of exposure
- Relationship between exposure and effects
- Human Factors
- Suitability of preventive measures
- Ability to neutralize or circumvent the preventive measures
- Ability to maintain preventive measures
- Information for use

4. Risk assessment. Chapter 8 of the standard

EXTRACTS OF EN ISO 14121-1

After estimating the risk should carry out risk assessment in order to determine it is necessary to reduce risk, If it is necessary to reduce the risk, then you must select and apply appropriate preventive measures, by repeating the procedure. As part of this iterative process, the designer must verify that the application of new preventive measures, will generate additional hazards or other risks are increased. If new hazards are created, these will be added to the list of hazards identified and appropriate preventive measures will be required to run them.

5. Documentation. Chapter 9 of the standard

EXTRACTS OF EN ISO 14121-1

The documentation on the risk assessment should test the procedure to be followed and the results that have been reached.

CHAPTER 8. RISK EVALUATION. FUNCTIONAL SAFETY BY EN 62061 AND EN 13849

Currently industrial applications demand ever more security, it is easy to deduce that when an application covers all the recommendations and regulations for protection of breakdowns and security, the probability of breakdowns is reduced drastically justifying the investment in quality equipment under the strictest standards.

The following standards for evaluate the level of security systems:

EN ISO 954-1: 03-1997: Safety related parts of control systems of machines. - Part 1: General principles for design.

EN ISO 13849-1:12-2007: Safety related parts of control systems of machines. - Part 1: General principles for design.

EN 62061: 10-2005: Safety of machinery-Functional safety of electrical control systems, electronic and programmable electronic safety-related.

EN 61508: 2002-11: Safety of machinery-Functional safety of electrical control systems, electronic and programmable electronic safety-related.

Part 1: General requirements

Part 2: Requirements electrocos control systems, electronic and programmable electronic safety-related

Part 3: Software requirements

Part 4: Terms and Abbreviations

Part 5: Examples to calculate the safety integrity level

Part 6: Principles of application of standards IEC 61508-2 and IEC 61508-3

FIGURE 24. Different standards with the main working information.

The standards that define **PL (performance levels)** and **SIL (safety integrity levels)** covering the systems control safety-related electrical, and produce the same or similar results, although through different methods. This providing users the option to choose the most suitable for your application or completeness and each standard offers comparable that are appropriate for users who are going.

The PL are related to the categories of security system, which first appeared in the '90s as part of the European standard **EN 954-1** that supported the policy of the EU machinery. It was decided that there should be a standard for the design of safety-related components of the control systems. The resulting standard presented a series of categories that are used to describe the structure of a safety-related circuit.

In terms of safety machinery standards of **EN 954-1**, Safety of machinery, parts of control systems relating to safety, the standard that has so far classified security levels, will be replaced by two standards co-exist for a while. The original standard is valid until 2010 to allow for a transition period to the new revised version.

In many cases, designers and installers of electronic security systems may choose to meet the requirements of **EN ISO 13849-1** or **EN 62061** and fully meet the EC Machinery Directive. The following image shows the design selection process and how the two standards are related.

Before these standards can be applied, you must have done a risk assessment of in accordance with the definitions in **EN ISO 14121** to identify potential risks and risk reduction measures. Best practices require the document and, in many cases, assessments are drafted to supplement the operating instructions of the equipment in the technical documentation.

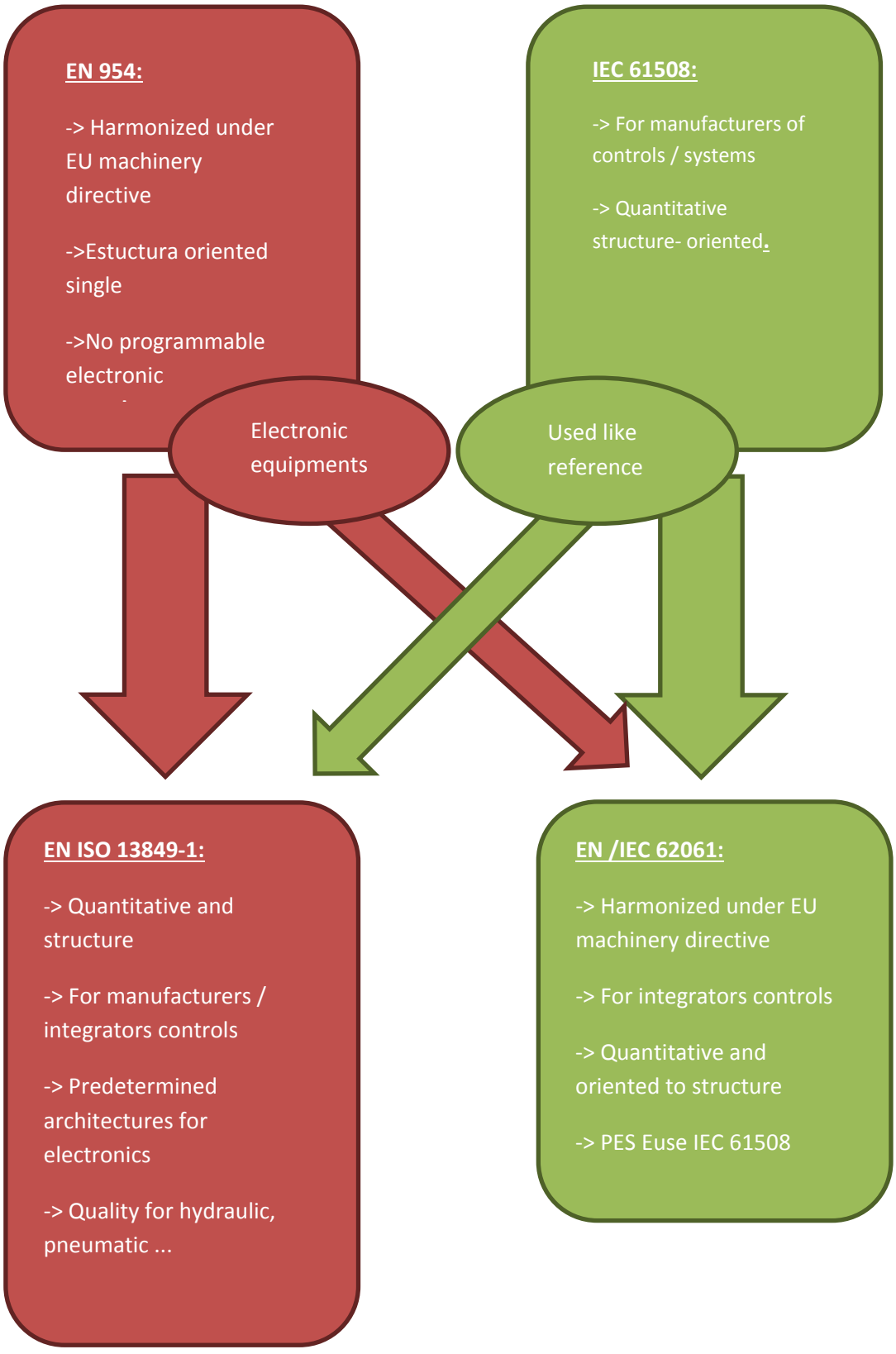


FIGURE 25. Different standards with the main information.

Before proceeding we should take into account certain abbreviations that are commonly used in these rules:

Designated Architecture: Structure of an default SPR / CS.

B10d: Number of switching operations when 10% of the sample fails.

CCF: Common cause failure.

CV: diagnostic coverage

DCavg: Coverage by diagnosis

MTBF: Mean time between failures

MTTFd: Mean time to dangerous failure

PFH: Probability failure per hour

PFHd: Probability of dangerous failure per hour

PL: Reliability level

PLr: Level of reliability required

SIL: Safety Integrity Level

SRP/CS: Safety related parts of control systems of machines

FIGURE 26. Definition about different abreviatures.

We briefly describe below the standard **``EN ISO 13849-1: 2008 - Safety of machinery: insurance components in control systems''**:

This standard is a revision of **EN 954-1** and provides safety requirements and guidelines for the design and integration of safety-related parts of the systems of control.

Introduced in 1996, **EN 954-1** was seen by some as too simple and insufficient approximation when forcing designers to evaluate the reliability of safety components. The new standard adds a quantitative to qualitative requirements of the above standard and includes the possibility of component failure of the security system. As to **EN 954-1**, using a risk estimate to determine the level of performance required (PLR). This is done with a risk graph as shown in the image.

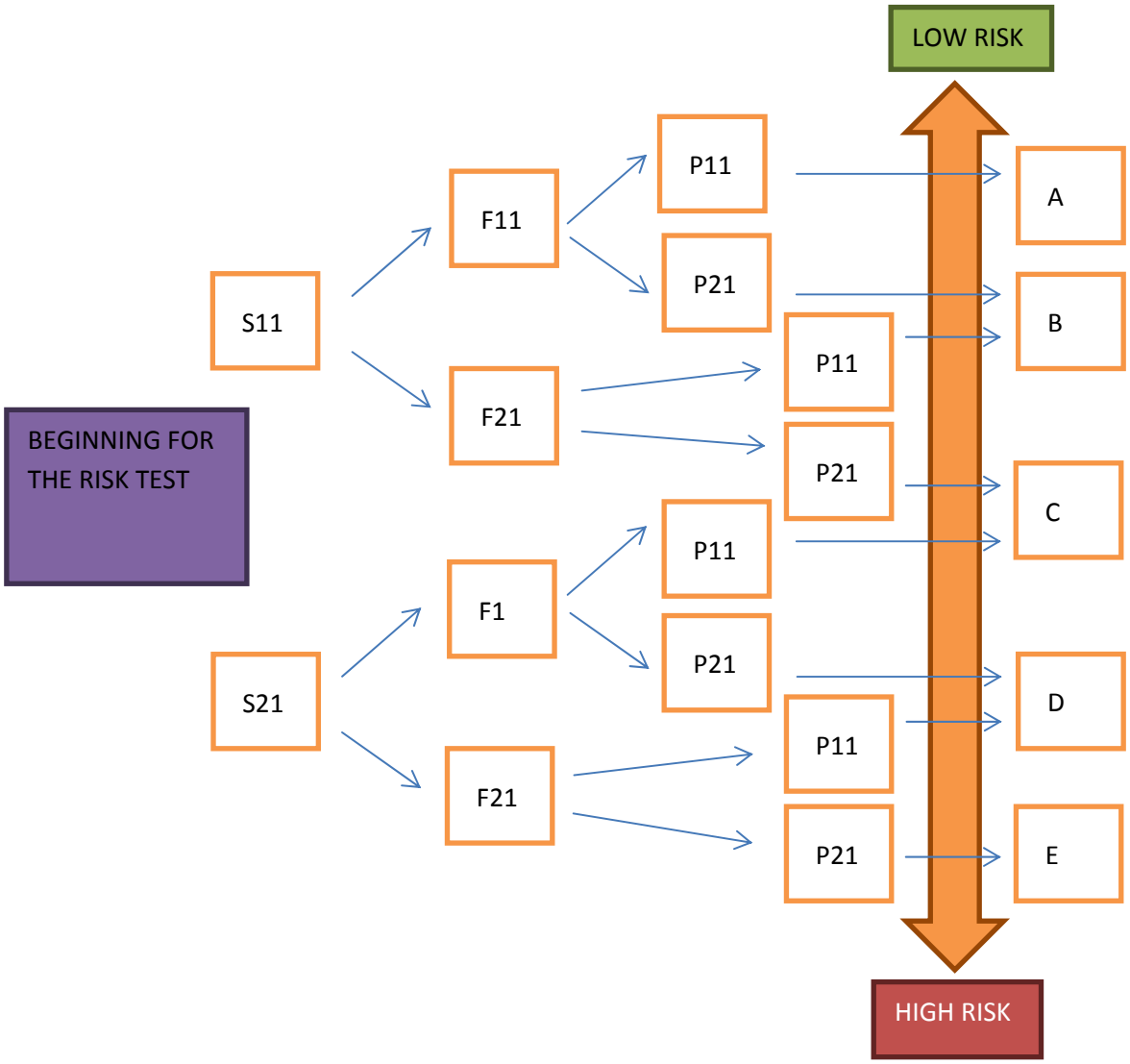


FIGURE 27. Steps to find the performance level required.

Severity of the wound (s): **S1**= minor injury

S2= serious injury, including death

Frequency and duration of exposure to danger (F): **F1**= infrequent or shortly

F2= often or too long

Possibilities of avoiding danger (P): **P1**=possible in certain circumstances

P2= rarely possible

FIGURE 28. Name of the abreviations written at figure 28.

NEW RICK CHART	
BACKGROUND	**EXECUTION**
The **UNE ISO 13 849-1** also uses a risk chart (see figure above), however, the consideration of the risk parameters already do not translate into control categories as in the **UNE 954-1**, but in the called reliability levels (**PL**). The **PL**, reliability level, refers to the ability of the safety-related control systems for machinery (**SRP / CS**) to perform a safety function to achieve the desired risk reduction, an approach that includes both quantitative and qualitative. Individual risk parameters of the new standard are unchanged with respect to the previous (injury severity, frequency and duration of exposure ...)	The corresponding confidence level (subdivided from **PL ``a´´** to **PL ``e´´**) reflects the different residual risks, expressed as the probability of failure per hour or PDHD serious. Therefore, the focus of the new standard takes into account the residual probability, ie including reliability engineering or a combination of deterministic and probabilistic visions. **PL** grades were selected to conform to safety integrity level **(SIL)** of **UNE IEC 61 508**, and may be associated with the control categories of **UNE 954-1**, although the match is not is accurate (as mentioned above), for example, the **category 1** corresponds (but not exactly) to PL b, category 2, the PL c, etc..
APPLICATION	
Consideration must be given each and every one of the security features of the machine arising from a risk analysis, for example, emergency stop, interlocking movable guards, etc.. The product is called **PLr** the graph consideration of risk (the letter **`` r''** means **`` required''**). The **PL** is a consideration global, and always refers to the chain of sensors (detection), the logical component (process) and (switch).	

TABLE 5. New risk char of new Directive 2006/42/EC

New aspects to have into account.

The result of the combination of deterministic and probabilistic approaches (the balance to which we referred above) is that for determining the PL must take into account the following aspects:

- Control category (roughly, as mentioned above) contained in the rule, is called predominantly `` designated architecture´´.
- The `` MTTFd´´ (mean time to dangerous failure).
- The ``diagnostic coverage ´´ (DC)
- The so-called `` Management common cause failures´´ (CCF)

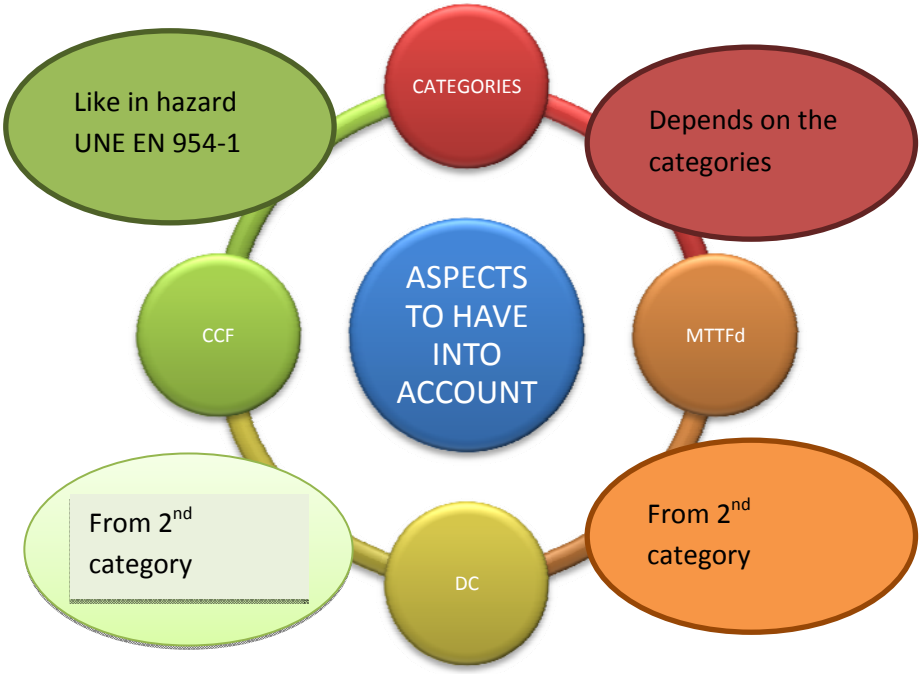


FIGURE 29. Aspect to have in account to know the risk of an instalation.

There are also measures to address system failures, a prerequisite already present in the **UNE ISO 13849-1**. Its origin is the failure of the theory of reliability engineering, which distinguishes between coincident failures (see **MTTFd**) and systematic, among others.

Systematic failures are deterministic causes do not coincide, and can only be removed by modifications in the design, production, operation sequences or similar factors.			
A selection of those in the UNE ISO 13849-2	Protection against influences from the environment	Typical computer information measures (control, review of programs ...)	Protection of data communications

TABLE 6. System failures in an installation.

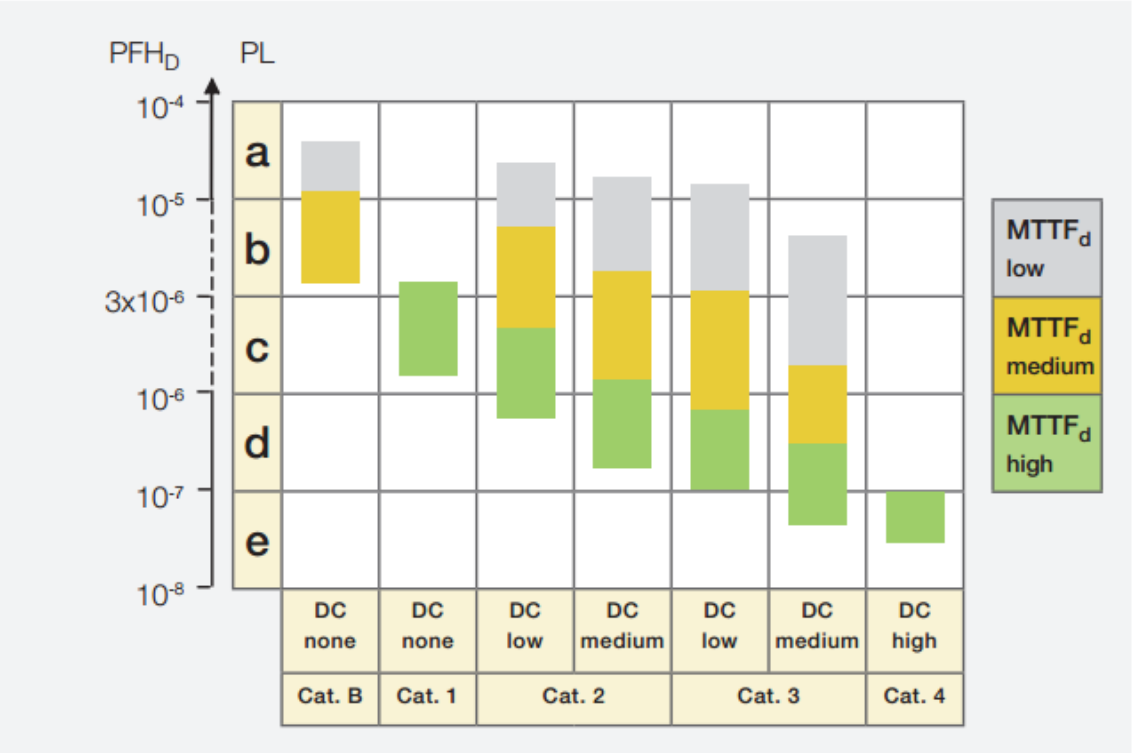
APPLICATION

Consideration must be given each and every one of the security features of the machine arising from a risk analysis, such as emergency stop, interlocking movable guards, etc.. **PLr** is called the product graph consideration of risk (the letter`` **r´´** means required).

PL is a global consideration, and always refers to the chain of sensors (detection), the logical component (process) and (switch).

THE LEVEL OF RELIABILITY IN REPLACEMENT OF THE CONTROL CATEGORY

The result of the analysis of 1 to 4 (ie, the analysis of the designated temperature, the channel MTTFd, DC and CCF) enter a block diagram from which to obtain the level of reliability achieved.



The relationship between categories, the DC_{avg}, $MTTF_d$ for each channel and PL. The table also shows the PFH_D-range that corresponds to each PL.

FIGURE 30. Chat to find the performance level required.

This means that a PL``e´´ requires a structure that corresponds to Category 4, a channel MTTFd `` high´´ and DC equally ``high´´ (DCavg concept corresponds to the average coverage of diagnosis).

If, however, the aim is the reduction of risk reaches a PL `` c´´ or ``d´´ may be selected various design possibilities, eg to a PL `` d´´ a structure according the category 2, a MTTFd `` high'' and `` half´´ DC. From the category 2 should always be considered the CCF factor.

Because the boundaries between different PL diagram do not exactly match the categories, it allows a simpler (the norm is a table instead of a graph).

In general terms, the UNE ISO 13849-1 adopts a four-phase approximation for the design of control systems related to security.

1. perform a risk assessment (EN ISO 14121)

2. for identified risks, assign the appropriate security measures for the performance level (PLr)

3. develop a suitable system architecture for performance level (PL)

4. validate the design to ensure it meets the requirements of the initial risk assessment

The last step involves the use of the manufacturer's data for the reliability of the components, including the calculation of the mean time to dangerous failure occurs (MTTFd) and the ability to diagnose and representing common mode failure of components.

Late 70's electronic systems were introduced in the world of mechanical engineering. Initially used only functions unrelated to safety, but at present, many of the security functions performed by the machine control systems are performed through LSI / VLSI, ASIC, PLCs, microcontrollers, etc. .

Because it became apparent, was necessary to have a new standard that will covering all aspects of the modern control system. The result was IEC61508: 1999, ``Functional safety of safety-related programmable electronics / electronics / electrical´´. This was followed in 2005 by **UNE 62061**, ``Safety of machinery-Functional safety of safety-related systems, programmable electronics / electronics / electrical´´. This standard covers complex machinery systems and, as IEC61508, provides the concept of safety integrity levels or SIL (another way of classifying the system performance).

We will briefly describe the ``**UNE 62061 - Safety of Machinery: Functional safety of electrical control systems, electronic and programmable:´´**

Electronic control systems on machinery safety play an increasing role in ensuring global security of the machines and used more and more often complex electronic technology.

UNE 62061 is an industry standard of machinery based on the **UNE 61508** (Functional safety of safety-related electrical, electronic and programmable) for

companies that have been designing these systems according to standard **UNE 61508** experience a relatively easy transition to the new standard.

The **UNE 62061** describes both the amount of risk that should be reduced and the ability of a control system to reduce this risk in terms of safety integrity level **(SIL).** There are three SIL employed in the field of machinery, **SIL1** being the lowest and the highest **SIL3**. Risks of high magnitude can occur in other sectors and in the process industry and for that reason, the standard **UNE 61508** and sector specific standard processes (**UNE 61511**) include the **SIL4.**

To determine a required level of **SIL** should take into account the consequences and a number of possible risk. Descriptive factors are:

1. Frequency or endurance. **Fr**
2. Possibility of the dangerous situation. **Pr**
3. Possible avoidance. **Av**

Consequences	Severity Se	Class Cl					Frequency and duration, Fr		Probability of hzd. event, Pr		Avoidance Av	
		3 - 4	5 - 7	8 - 10	11 - 13	14 - 15						
Death, losing an eye or arm	4	SIL 2	SIL 2	SIL 2	SIL 3	SIL 3	<= 1 hour	5	Common	5		
Permanent, losing fingers	3		OM	SIL 1	SIL 2	SIL 3	> 1 h - <=day	5	Likely	4		
Reversible, medical attention	2			OM	SIL 1	SIL 2	>1day - <= 2wks	4	Possible	3	Impossible	5
Reversible, first aid	1				OM	SIL 1	> 2wks - <= 1 yr	3	Rarely	2	Possible	3
							> 1 yr	2	Negligible	1	Likely	1

FIGURE 31. Char to find the SIL required.

PROCEDURE:

1. Determine the consequences with severity, **Se**
2. Determine Frequency **Fr,** possibility **Pr**, and Avoidance **Av**
3. Class **Cl= Fr+ Pr+ Av**
4. Find intersection line between Se and Cl, this one says us what is the required **SIL**.

FIGURE 32. Procedure to find SIL required.

SILs retain many of the principles of category system but also add a level of detail and definition that better addresses modern control and security architectures. are used to determine the functional safety quantifying the probability of occurrence of a fault in a device while performing its safety function. There are levels for machinery train, **SIL3** is the most reliable, and **SIL1** the least. Along with assessments in the background, the SIL also use a combination of technical factors to determine the level or classification, including the average probability of dangerous failure on demand (**PFHD)** and security features required for a process.

It is the work that occurs in the background that distinguishes the **SIL**. With regard to functional safety, appropriate management systems should be on your side to ensure that the right people with the right level of expertise is working on the job in question.

It is also necessary to deal with the specifications of security requirements. These are used to determine exactly what security requirements must be met. It deals with the components and the systems with respect to their design, validation and specification on the project life cycle, while also contemplates any environmental influence, as well as other factors that may affect the optimal system.

The final addition is the way to address the systems and subsystems, with UNE standards like **IEC 61508** covering complex subsystems such as safety PLCs. The first subdivision on measures to avoid systematic breakdowns and subsequent action to control the complex secondary system in the event that a malfunction occurs in the system. The second one focuses on the reliability of the system, using the probability of occurrence of dangerous breakdowns per hour (**PFHD**) as a measure.

The end subdivision deals with architectural constraints. An example would be the combination of the features of fault tolerance in a secondary system and balance functions compared with existing diagnoses, with a high tolerance and significant diagnoses that result in the highest.

There are many other factors to determine the levels of **SIL**, and the methods of formal software design, modification and validation techniques, however, still more highlight the major differences between the categories and **SIL**. In general, whether they use a **PL**, a **SIL** or a combination of both, the choice should be related to the complexities of the systems and, for this reason, perhaps could provide guidance on which method to adopt.

CHAPTER 9. EN ISO 13859. SECURITY DISTANCES.

UNE ISO 13857:2008 Safety of machinery. Safety distances to prevent danger zones being reached by the upper limbs and lower limbs.

This document is a standard type B

This International Standard establishes values for safety distances, in an industrial environment such as public, in order to prevent danger zones being reached by the machines. Safety distances are appropriate for protective structures. This International Standard also gives information about the distances to prevent free access of the lower limbs.

This international standard covers people aged less than 14 years.

1. Safety distances to prevent the access of upper limps. Point 4.2 of the standard

1.1 Reach upwards

- Figure shows the safety distances to reach upwards.

Right hand = Dangerous area
and high of the dangerous area

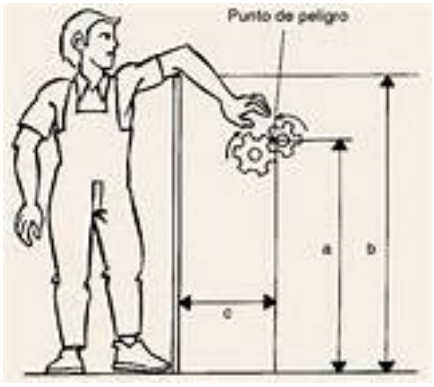
Floor = Reference

FIGURE 33. Safety distance reach upwards.

- If the risk in the dangerous area is low, the height of the danger zone, h, must be equal to or greater than 2500mm.
- If the risk is high danger zone, the height of the danger zone, h, must be equal to or greater than 2700mm.

1.2 Scope over protective structures

- The figure shows the safety distance to reach over protective structure.



A = high of the dangerous area

B = high of the protective structure

C = Safety distance horizontal to the danger zone

FIGURE 34. Safety distance scope over protective structures.

Table 1 (case of low risk)

Unit: mm

Height of danger zone, a	Height of protective structure, b[1]								
	1 000	1 200	1 400	1 600	1 800	2 000	2 200	2 400	2 500
	Horizontal distance to danger zone, c								
2 500[2]	–	–	–	–	–	–	–	–	–
2 400	100	100	100	100	100	100	100	100	–
2 200	600	600	500	500	400	350	250	–	–
2 000	1 100	900	700	600	500	350	–	–	–
1 800	1 100	1 000	900	900	600	–	–	–	–
1 600	1 300	1 000	900	900	500	–	–	–	–
1 400	1 300	1 000	900	800	100	–	–	–	–
1 200	1 400	1 000	900	500	–	–	–	–	–
1 000	1 400	1 000	900	300	–	–	–	–	–
800	1 300	900	600	–	–	–	–	–	–
600	1 200	500	–	–	–	–	–	–	–
400	1 200	300	–	–	–	–	–	–	–
200	1 100	200	–	–	–	–	–	–	–
0	1 100	200	–	–	–	–	–	–	–

Notes 1) Protective structures less than 1 000 mm in height are not included because they do not sufficiently restrict movement of the body.

2) For danger zones above 2 500 mm, refer to **4.2**.

TABLE 7. Horizontal distance to danger.

Table 2 (case of high risk)

Unit: mm

Height of danger zone, a	Height of protective structure, b[1]									
	1 000	1 200	1 400[2]	1 600	1 800	2 000	2 200	2 400	2 500	2 700
	Horizontal distance to danger zone, c									
2 700[3]	—	—	—	—	—	—	—	—	—	—
2 600	900	800	700	600	600	500	400	300	100	—
2 400	1 100	1 000	900	800	700	600	400	300	100	—
2 200	1 300	1 200	1 000	900	800	600	400	300	—	—
2 000	1 400	1 300	1 100	900	800	600	400	—	—	—
1 800	1 500	1 400	1 100	900	800	600	—	—	—	—
1 600	1 500	1 400	1 100	900	800	500	—	—	—	—
1 400	1 500	1 400	1 100	900	800	—	—	—	—	—
1 200	1 500	1 400	1 100	900	700	—	—	—	—	—
1 000	1 500	1 400	1 000	800	—	—	—	—	—	—
800	1 500	1 300	900	600	—	—	—	—	—	—
600	1 400	1 300	800	—	—	—	—	—	—	—
400	1 400	1 200	400	—	—	—	—	—	—	—
200	1 200	900	—	—	—	—	—	—	—	—
0	1 100	500	—	—	—	—	—	—	—	—

Notes 1) Protective structures less than 1 000 mm in height are not included because they do not sufficiently restrict movement of the body.

2) Protective structures lower than 1 400 mm should not be used without additional safety measures.

3) For danger zones above 2 700 mm, refer to **4.2**.

TABLE 8. Height of performance structure

1.3 Scope in all directions with movement limit

For upper limbs accesses table3 is used considering the following conditions:

- This table applies to people over 14 years measuring at least 1.4 m.
- Distances can be used up to 850mm lower (see Table 4) when the obstacle that restricts the movement has a length of 300mm minimum.

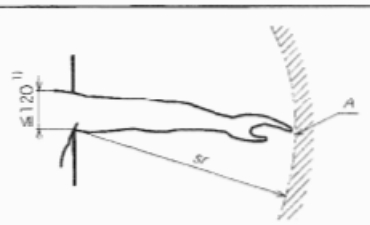
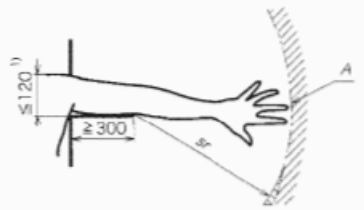
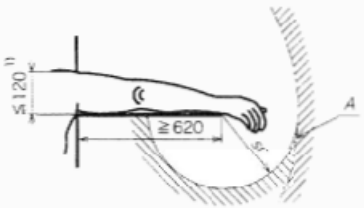
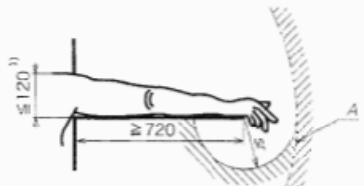
Limitation of movement	Safety distance, *sr*	Illustration
Limitation of movement only at shoulder and armpit	≥ 850	
Arm supported up to elbow	≥ 550	
Arm supported up to wrist	≥ 230	
Arm and hand supported up to knuckle joint	≥ 130	

TABLE 9. Scope in all directions with movement limit.

1.4 Scope through openings

To access openings upper limb was employed by Table 4, taking into account the following conditions:

- This table applies to people over 14 years.
- For openings greater than 120mm, Table 3 should be used.

Table 4

Unit: mm

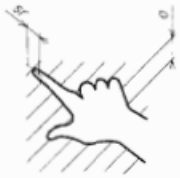
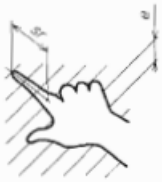
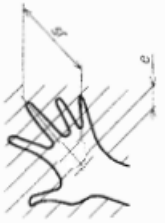
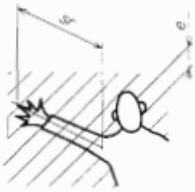
Part of body	Illustration	Opening	Safety distance, *sr*		
			Slot	Square	Round
Finger tip		$e \leq 4$	≥ 2	≥ 2	≥ 2
		$4 < e \leq 6$	≥ 10	≥ 5	≥ 5
Finger up to knuckle joint or hand		$6 < e \leq 8$	≥ 20	≥ 15	≥ 5
		$8 < e \leq 10$	≥ 80	≥ 25	≥ 20
		$10 < e \leq 12$	≥ 100	≥ 80	≥ 80
		$12 < e \leq 20$	≥ 120	≥ 120	≥ 120
		$20 < e \leq 30$	≥ 850 [1]	≥ 120	≥ 120
Arm up to junction with shoulder		$30 < e \leq 40$	≥ 850	≥ 200	≥ 120
		$40 < e \leq 120$	≥ 850	≥ 850	≥ 850

TABLE 10. Scope through openings.

CHAPTER 10. STOP FUNCTION

UNE 60204-1 in paragraph 9.2.2 requires each machine incorporates a stop function.

There are three stop categories:

- Category 0: stopping by immediate removal of power to the actuators
- Category 1: controlled stop maintaining the energy available in the actuators of the machine to allow the stop. The power supply is not disrupts until the stop has occurred.
- Category 2: controlled stop maintaining the energy available in the actuators

Notes:

- For a Category 1 stop maximum time to produce the disconnection of energies is recommended that no more than 30 seconds. This type of stop is usually applied in installations where a stop category 0 would mean a higher risk for immediate disconnection of energies could generate an accident or breakdown that could trigger it.
- Solutions according to emergency stop category 2 must be applied with great caution. In fact, solutions of this type are held only with special safety systems such as a safety PLC or a programmable module.

CHAPTER 12. COMERCIAL ELEMENTS OF SAFETY

In this chapter we will develop a series of sections which explain the security business elements that exist in the market.

Its use and is essential for safety tecnic involved in modifications to adapt work equipment regulations, or to the technician who develops new equipment or automated systems.

Many of these items are approved and will be precisely these that certify (if you strictly follow the manufacturer's instructions) that the security system has implemented certain security category.

1. Safety switches

Safety switches are very important to certify the existence of movable guards in working position when the production process is in progress.

1.1 Safety switches without locking services.

Safety switches without locking device placed in a cell protection certify that there is in the working position when starting the production of the machine as it is not placed is impossible to start the cycle. If during the work cycle occurred opening the machine will stop. We must take into account when installing this type of switch, the opening during operation of the team should not be hazardous to the worker, for example, its installation should be done in such a way that once the opening occurs of protection, stop mobile elements is sufficiently fast so that the worker does not reach the danger zone with these elements in motion.

The Rockwell Tongue Interlock Switches allow the head of the switch to rotate, offering different options on how you can operate the switch and mount it on the guard. This flexibility offers the best fit for your applications.

FIGURE 35. ROCKWELL safety switches without locking services.

These are the different models of devices:

- 440K Cadet 3
- 440K Elf Miniature
- 440K MT-GD2
- 440K Trojan 5 & 6 Universal
- 440K Trojan T15 & T15-GD2

1.2 Non-contact switches.

They consist of two elements that recognize each other without contact. You can code and have great difficulty mocked. They are very useful for any type of fencing as its installation is very simple and has a high tolerance of alignment.

They are used in applications where the rules requires high security category, when heavy soiling or whether to meet strict hygiene regulations. Also are used in applications that pose problems for precise guidance of doors, doors that subject to strong vibration machines and require high boot tolerances.

Rockwell Non-contact Interlock Switches help you to protect personnel and equipment. At the same time, flexibility and productivity are points that you must also consider as you design your safety system. For non-contact interlocks, no physical contact (under normal conditions) takes place between the switch and actuator.

FIGURE 36. ROCKWELL, non contact switch.

These are the different models that Rockwell have:

- 440N Ferrogard 1, 2, 20, 21
- 440N Ferrogard 3, 4, 5
- 440N Ferrogard 6, 9, 10, 13, 14
- 440N Ferrogard GD2
- 440N Ferrogard GS1, GS2
- 440N Magnetically Coded
- 440N SensaGuard
- 440N Sipha Sensors

2. Security modules.

Security modules are fundamental within the safety of a team. These security modules certify proper operation of a security system and adecuate integrated into the security level for which they are approved.

Is very important for safety circuits in which you install a control module are independent of team maneuver, so that failures of this do not affect the safety of the machine.

Is very important for the security level for which the device is approved safety circuits segur determined by the manufacturer.

There are the following security modules.

- For emergency stop control
- To control safety switches
- To control sensitive mats
- Control of sensitive edges
- Control system for two-hand or desk bimanual
- Optoelectronic systems to control

3. Sensible edges.

Safety sensitive edges are used for the protection of moving parts in the points at which you can produce crushing, shearing or impact. Widely used in automated moving parts that can cause entrapment protection such as motorized mobile.

Usually of rubber or neoprene and are variably depending on the manufacturer and the different models, but are generally as a roe pipe inside which a conductor or conductors located responsive to the contract, such that when a pressure in any edge point occurs stop element to which this partner.

The new ROCKWELL sensible edge use a combination of non-conductive rubber and flexible wire-cored conductive rubber bonded together so they keep bouncing back into shape even after repeated compressions.

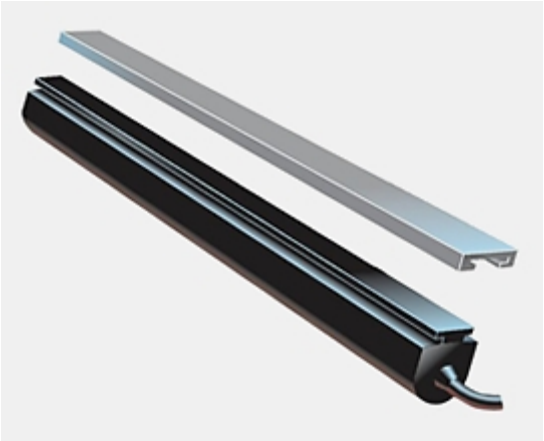


FIGURE 37.ROCKWELL, sensible edge.

4. Safety mats.

Consist of a number of interconnecting pressure- sensitive safety mats and a monitoring control unit that provide a system for area detection.

Sensitive mats are electrical switches pressure sensitive area. Through these devices can detect the presence of unauthorized personnel working in hazardous areas. Keep in mind that the maximum safety category can get is 3 according to EN 954. It is very important when designing the implementation of sensitive carpet to protect access to an area that we consider dangerous, considering the safety distances set out in EN 999, to prevent persons entering the danger zone carpet may come before the full stop the dangerous movement.

They are usually designed to work under severe conditions, like mechanical, chemical or thermal.

ROCKWELL safety mats are pressure-sensitive safeguarding products that we designed to detect the presence of people on the sensing surfaces. These mats have two conductive hardened steel plates that are held apart by non-conductive compressible separators. We offer standard configurable and custom mats, each with edge trim options.

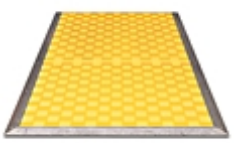


FIGURE 38. ROCKWELL ,safety mat.

5. Safety lasers scanners.

Are type 3 opto-electronic devices that protect personnel or equipment by detecting them in its sensing field. Operating on the 'time of flight' principle, the scanners emit pulses of eye-safe infrared laser light over a 190-degree arc, then receive and process the light reflected off of intrusions in the sensing field to determine the position and distance to the object. When an object is detected, the scanners send a stop signal to the protected machine.

FIGURE 39. ROCKWELL, safety laser scanner..

6. Hand detection safety sensor.

Is a compact safety sensor system which operates based on image processing technology. The safety sensing function is performed by a single image sensing device viewing a single two-dimensional image against a passive pattern as the background. The detection principle is based on an object of a certain resolution blocking the view of the pattern from the image-sensing device.

FIGURE 40. ROCKWELL, hand detection safety sensor.

7. Sensitive controls.

The controls sensory or also called deadman used when the operator has to work at some particular moment in a high risk area. It is used for verification actions, maintenance and adjustment or setting, during which you have deleted existing security levels and there is no other device that can ensure the protection of the operator.

In these cases the operator access to the danger zone with sensitive control that must be pressed at all times, so that you release, the team that operates in this area of danger is immediately stopped as if he had made an emergency stop.

FIGURE 41. ROCKWELL, 440J grip enabling switch.

ANEX I . DIRECTIVE 2006/42/CE

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (3),

Whereas:

(1) Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (4) codified Directive 89/392/EEC (5). Now that new substantial amendments are being made to Directive 98/37/EC, it is desirable, in order to clarify matters, that that Directive should be recast.

(2) The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Community economy. The social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance.

(3) Member States are responsible for ensuring the health and safety on their territory of persons, in particular of workers and consumers and, where appropriate, of domestic animals and goods, notably in relation to the risks arising out of the use of machinery.

(1) OJ C 154 E, 29.5.2001, p. 164.

(4) In order to ensure legal certainty for users, t this Directive and the concepts relating to its should be defined as precisely as possible.

(5) The Member States' mandatory provisions construction site hoists intended for lifting persons and goods, which are often supplem facto compulsory technical specifications voluntary standards, do not necessarily lead levels of health and safety but, because of t ties, do nevertheless constitute barriers to t the Community. Moreover, the national syst conformity assessment and certification machines diverge considerably. It is therefo not to exclude from the scope of this Directi tion site hoists intended for lifting persons and goods.

(6) It is appropriate to exclude from the scope o tive weapons, including firearms, that are Council Directive 91/477/EEC of 18 Jun control of the acquisition and possession of the exclusion of firearms should not apply cartridge-operated fixing and other impact designed for industrial or technical purpose necessary to provide for transitional ar enabling Member States to authorise the pla market and putting into service of such manufactured in accordance with national p force upon adoption of this Directive, incl implementing the Convention of 1 July 1 Reciprocal Recognition of Proofmarks on S Such transitional arrangements will also enab pean standardisation organisations to draf ensuring the safety level based on the state o

(7) This Directive does not apply to the lifting o means of machines not designed for the persons. However, this does not affect t Member States to take national measures, in with the Treaty, with respect to such mach

covered by Directive 2003/37/EC.

(9) Market surveillance is an essential instrument inasmuch as it ensures the proper and uniform application of Directives. It is therefore appropriate to put in place the legal framework within which market surveillance can proceed harmoniously.

(10) Member States are responsible for ensuring that this Directive is effectively enforced on their territory and that the safety of the machinery concerned is, as far as possible, improved in accordance with its provisions. Member States should ensure their capacity to carry out effective market surveillance, taking account of guidelines developed by the Commission, in order to achieve the proper and uniform application of this Directive.

(11) In the context of market surveillance, a clear distinction should be established between the disputing of a harmonised standard conferring a presumption of conformity on machinery and the safeguard clause relating to machinery.

(12) The putting into service of machinery within the meaning of this Directive can relate only to the use of the machinery itself for its intended purpose or for a purpose which can reasonably be foreseen. This does not preclude the laying down of conditions of use external to the machinery, provided that it is not thereby modified in a way not specified in this Directive.

(13) It is also necessary to provide for an adequate mechanism allowing for the adoption of specific measures at Community level requiring Member States to prohibit or restrict the placing on the market of certain types of machinery presenting the same risks to the health and safety of persons either due to shortcomings in the relevant harmonised standard(s) or by virtue

account of the state of the art at the time
and of technical and economic requiremer

(15) Where the machinery may be used by a
is to say, a non-professional operator, th
should take account of this in the design
tion. The same applies where a machi
used to provide a service to a consumer.

(16) Although the requirements of this Di
apply to partly completed machinery in t
is nevertheless important that the free
such machinery be guaranteed by mean
procedure.

(17) For trade fairs, exhibitions and such lik
possible to exhibit machinery which does
requirements of this Directive. Howe
parties should be properly informed that
does not conform and cannot be pur
condition.

(18) This Directive defines only the essential he
requirements of general application, supp
number of more specific requirements fo
gories of machinery. In order to help m
prove conformity to these essential requir
allow inspection of conformity to the es
ments, it is desirable to have standards t
nised at Community level for the preve
arising out of the design and construction
These standards are drawn up by private-
should retain their non-binding status.

(19) In view of the nature of the risks involve
machinery covered by this Directive,
assessing conformity to the essential he
requirements should be established. The
should be devised in the light of the exten
inherent in such machinery. Consequently
of machinery should have its appropriat

(21) The CE marking should be fully recognised as being the only marking which guarantees that machinery conforms to the requirements of this Directive. All other markings which are likely to mislead third parties as to the meaning or the form of the CE marking, or both, should be prohibited.

(22) In order to ensure the same quality for the CE marking and the manufacturer's mark, it is important that they be affixed according to the same techniques. In order to avoid confusion between any CE markings which might appear on certain components and the CE marking corresponding to the machinery, it is important that the latter marking be affixed alongside the name of the person who has taken responsibility for it, namely the manufacturer or his authorised representative.

(23) The manufacturer or his authorised representative should also ensure that a risk assessment is carried out for the machinery which he wishes to place on the market. For this purpose, he should determine which are the essential health and safety requirements applicable to his machinery and in respect of which he must take measures.

(24) It is essential that, before drawing up the EC declaration of conformity, the manufacturer or his authorised representative established in the Community should prepare a technical construction file. However, it is not essential that all documentation should be permanently available in material form, but it must be possible to make it available on request. It need not include detailed plans of subassemblies used for the manufacture of machinery, unless knowledge of such plans is essential in order to ascertain conformity with the essential health and safety requirements.

(25) The addressees of any decision taken under this Directive should be informed of the reasons for such a decision and of the legal remedies open to them.

(26) Member States should provide for penalties applicable to

(28) Since the objective of this Directive, r
down the essential health and safety r
relation to design and manufacture in or
the safety of machinery placed on the ma
sufficiently achieved by the Member Sta
better achieved at Community level, th
may adopt measures, in accordance with
subsidiarity as set out in Article 5 of
accordance with the principle of propor
out in that Article, this Directive does
what is necessary in order to achieve that

(29) In accordance with point 34 of the In
Agreement on better law-making (2), Mem
encouraged to draw up, for themselves an
ests of the Community, their own tables
far as possible, the correlation between
and the transposition measures, and t
public.

(30) The measures necessary for the impleme
Directive should be adopted in accordanc
Decision 1999/468/EC of 28 June 199
the procedures for the exercise of implem
conferred on the Commission (3),

HAS ADOPTED THIS DIRECTIVE:

Article 1

Scope

1. This Directive applies to the following proc

(a) machinery;

(b) interchangeable equipment;

(c) safety components;

(d) lifting accessories;

(e) chains, ropes and webbing;

(b) specific equipment for use in fairgrounds and/or amusement parks;

(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;

(d) weapons, including firearms;

(e) the following means of transport:

— agricultural and forestry tractors for the risks covered by Directive 2003/37/EC, with the exclusion of machinery mounted on these vehicles,

— motor vehicles and their trailers covered by Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers (1), with the exclusion of machinery mounted on these vehicles,

— vehicles covered by Directive 2002/24/EC of the European Parliament and of the Council of 18 March 2002 relating to the type-approval of two or three-wheel motor vehicles (2), with the exclusion of machinery mounted on these vehicles,

— motor vehicles exclusively intended for competition, and

— means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport;

(f) seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;

(g) machinery specially designed and constructed for military or police purposes;

(h) machinery specially designed and constructed for research purposes for temporary use in laboratories;

(i) mine winding gear;

— audio and video equipment,

— information technology equipment,

— ordinary office machinery,

— low-voltage switchgear and control gear

— electric motors;

(l) the following types of high-voltage electrica

— switch gear and control gear,

— transformers.

Article 2

Definitions

For the purposes of this Directive, 'machinery products listed in Article 1(1)(a) to (f).

The following definitions shall apply:

(a) 'machinery' means:

— an assembly, fitted with or intended to drive system other than directly app animal effort, consisting of linked parts at least one of which moves, and w together for a specific application,

— an assembly referred to in the first inde the components to connect it on site energy and motion,

— an assembly referred to in the first and ready to be installed and able to func only if mounted on a means of transpo a building or a structure,

— assemblies of machinery referred to in and third indents or partly compl referred to in point (g) which, in orde same end, are arranged and controll function as an integral whole,

— which serves to fulfil a safety function,

— which is independently placed on the market,

— the failure and/or malfunction of which endangers the safety of persons, and

— which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.

An indicative list of safety components is set out in Annex V, which may be updated in accordance with Article 8(1)(a);

(d) 'lifting accessory' means a component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market; slings and their components are also regarded as lifting accessories;

(e) 'chains, ropes and webbing' means chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;

(f) 'removable mechanical transmission device' means a removable component for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one product;

(g) 'partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies;

(h) 'placing on the market' means making available for the first

(j) 'authorised representative' means any person established in the Community wh written mandate from the manufacturer t behalf all or part of the obligations connected with this Directive;

(k) 'putting into service' means the first use, purpose, in the Community, of machinery Directive;

(l) 'harmonised standard' means a non-bindin fication adopted by a standardisation b European Committee for Standardisation pean Committee for Electrotechnical (CENELEC) or the European Telecommuni Institute (ETSI), on the basis of a rem Commission in accordance with the proc in Directive 98/34/EC of the European P the Council of 22 June 1998 laying down the provision of information in the field dards and regulations and of rules on Inf services (1).

Article 3

Specific Directives

Where, for machinery, the hazards referred t wholly or partly covered more specifically by Directives, this Directive shall not apply, apply, to that machinery in respect of such date of implementation of those other Directiv

Article 4

Market surveillance

1. Member States shall take all appropri ensure that machinery may be placed on the m

completed machinery with the provisions set out in paragraphs 1 and 2.

4. Member States shall define the tasks, organisation and powers of the competent authorities referred to in paragraph 3 and shall notify the Commission and other Member States thereof and also of any subsequent amendment.

Article 5

Placing on the market and putting into service

1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:

(a) ensure that it satisfies the relevant essential health and safety requirements set out in Annex I;

(b) ensure that the technical file referred to in Annex VII, part A is available;

(c) provide, in particular, the necessary information, such as instructions;

(d) carry out the appropriate procedures for assessing conformity in accordance with Article 12;

(e) draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery;

(f) affix the CE marking in accordance with Article 16.

2. Before placing partly completed machinery on the market, the manufacturer or his authorised representative shall ensure that the procedure referred to in Article 13 has been completed.

3. For the purposes of the procedures referred to in Article 12, the manufacturer or his authorised representative shall have, or shall have access to, the necessary means of ensuring that the machinery satisfies the essential health and safety requirements set out in Annex I.

Article 6

Freedom of movement

1. Member States shall not prohibit, restr
placing on the market and/or putting into se
tory of machinery which complies with this D

2. Member States shall not prohibit, restr
placing on the market of partly completed
the manufacturer or his authorised repres
declaration of incorporation, referred to in
Section B, stating that it is to be incorporate
or assembled with other partly completed n
machinery.

3. At trade fairs, exhibitions, demonstratio
Member States shall not prevent the showing
partly completed machinery which does no
Directive, provided that a visible sign clearl
does not conform and that it will not be mad
has been brought into conformity. Furthermo
strations of such non-conforming mach
completed machinery, adequate safety measu
to ensure the protection of persons.

Article 7

Presumption of conformity and harmon

1. Member States shall regard machiner
marking and accompanied by the EC declarat
the content of which is set out in Annex II,
as complying with the provisions of this Dire

2. Machinery manufactured in conformit
nised standard, the references to which have
the *Official Journal of the European Union*, sha
comply with the essential health and sa
covered by such a harmonised standard.

dure referred to in Article 22(3), may take any appropriate measure to implement the provisions relating to the following points:

(a) updating of the indicative list of safety components in Annex V referred to in point (c) in Article 2;

(b) restriction of the placing on the market of machinery referred to in Article 9.

2. The Commission, acting in accordance with the procedure referred to in Article 22(2), may take any appropriate measure connected with the implementation and practical application of this Directive, including measures necessary to ensure cooperation of Member States with each other and with the Commission, as provided for in Article 19(1).

Article 9

Specific measures to deal with potentially hazardous machinery

1. When, in accordance with the procedure referred to in Article 10, the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery with technical characteristics presenting risks due to the shortcomings in the standard or to make such machinery subject to special conditions.

When, in accordance with the procedure referred to in Article 11, the Commission considers that a measure taken by a Member State is justified, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery presenting the same risk by virtue of its technical characteristics or to make such machinery subject to special conditions.

2. Any Member State may request the Commission to

Procedure for disputing a harmonis

Where a Member State or the Commissio
harmonised standard does not entirely s
health and safety requirements which it co
set out in Annex I, the Commission or the
bring the matter before the committee set u
34/EC, setting out the reasons therefor. Th
deliver an opinion without delay. In the lig
tee's opinion, the Commission shall decide
publish, to publish with restriction, to ma
with restriction or to withdraw the referen
nised standard concerned in the *Official Jou*
Union.

Article 11

Safeguard clause

1. Where a Member State ascertains that
by this Directive, bearing the CE marking, a
EC declaration of conformity and used in a
intended purpose or under conditions which
foreseen, is liable to compromise the he
persons and, where appropriate, domestic a
it shall take all appropriate measures t
machinery from the market, to prohibit t
market and/or putting into service of such
restrict free movement thereof.

2. The Member State shall immediately in
sion and the other Member States of any s
cating the reasons for its decision and, in
the non-conformity is due to:

(a) failure to satisfy the essential requirem
Article 5(1)(a);

(b) incorrect application of the harmonised
to in Article 7(2);

(c) shortcomings in the harmonised sta
referred to in Article 7(2).

marking, the competent Member State shall take appropriate action against whomsoever has affixed the marking and shall so inform the Commission. The Commission shall inform the other Member States.

6. The Commission shall ensure that Member States are kept informed of the progress and outcome of the procedure.

Article 12

Procedures for assessing the conformity of machinery

1. The manufacturer or his authorised representative shall, in order to certify the conformity of machinery with the provisions of this Directive, apply one of the procedures for assessment of conformity described in paragraphs 2, 3 and 4.

2. Where the machinery is not referred to in Annex IV, the manufacturer or his authorised representative shall apply the procedure for assessment of conformity with internal checks on the manufacture of machinery provided for in Annex VIII.

3. Where the machinery is referred to in Annex IV and manufactured in accordance with the harmonised standards referred to in Article 7(2), and provided that those standards cover all of the relevant essential health and safety requirements, the manufacturer or his authorised representative shall apply one of the following procedures:

(a) the procedure for assessment of conformity with internal checks on the manufacture of machinery, provided for in Annex VIII;

(b) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3;

(c) the full quality assurance procedure provided for in Annex X.

Article 13

Procedure for partly completed m

1. The manufacturer of partly completed authorised representative shall, before placin ensure that:

(a) the relevant technical documentati Annex VII, part B is prepared;

(b) assembly instructions described in Annex

(c) a declaration of incorporation described Section B has been drawn up.

2. The assembly instructions and the de poration shall accompany the partly complet it is incorporated into the final machinery a part of the technical file for that machinery.

Article 14

Notified bodies

1. Member States shall notify the Commis Member States of the bodies which they carry out the assessment of conformity f market referred to in Article 12(3) and (4), specific conformity assessment procedures machinery for which these bodies have been identification numbers assigned to them b Commission. Member States shall notify th other Member States of any subsequent ame

2. The Member States shall ensure that are monitored regularly to check that they

5. Bodies meeting the assessment criteria laid down in the relevant harmonised standards, the references of which shall be published in the *Official Journal of the European Union*, shall be presumed to fulfil the relevant criteria.

6. If a notified body finds that relevant requirements of this Directive have not been met or are no longer met by the manufacturer or that an EC type-examination certificate or the approval of a quality assurance system should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate or the approval issued or place restrictions on it, giving detailed reasons, unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. In the event of suspension or withdrawal of the certificate or the approval or of any restriction placed on it, or in cases where intervention by the competent authority may prove necessary, the notified body shall inform the competent authority pursuant to Article 4. The Member State shall inform the other Member States and the Commission without delay. An appeal procedure shall be available.

7. The Commission shall provide for the organisation of an exchange of experience between the authorities responsible for appointment, notification and monitoring of notified bodies in the Member States, and the notified bodies, in order to coordinate the uniform application of this Directive.

8. A Member State which has notified a body shall immediately withdraw its notification if it finds:

(a) that the body no longer meets the criteria set out in Annex XI; or

(b) that the body seriously fails to fulfil its responsibilities.

The Member State shall immediately inform the Commission and the other Member States accordingly.

Article 16

CE marking

1. The CE conformity marking shall cor
'CE' as shown in Annex III.

2. The CE marking shall be affixed to the
legibly and indelibly in accordance with Anne

3. The affixing on machinery of markings
tions which are likely to mislead third
meaning or form of the CE marking, or bot
ited. Any other marking may be affixed
provided that the visibility, legibility and m
marking is not thereby impaired.

Article 17

Non-conformity of markin

1. Member States shall consider the follo
to conform:

(a) the affixing of the CE marking pursuan
on products not covered by this Directive

(b) the absence of the CE marking and/or
EC declaration of conformity for machine

(c) the affixing on machinery of a marking,
marking, which is prohibited under Artic

2. Where a Member State ascertains that
conform to the relevant provisions of this D
facturer or his authorised representative sh

of this Directive are required to treat as confidential information obtained in the execution of their tasks. More particularly business, professional and trade secrets shall be treated as confidential, unless the divulging of such information is necessary in order to protect the health and safety of persons.

2. The provisions of paragraph 1 shall not affect the obligations of the Member States and the notified bodies with regard to mutual exchange of information and the issuing of warnings.

3. Any decisions taken by the Member States and by the Commission in accordance with Articles 9 and 11 shall be published.

Article 19

Cooperation between Member States

1. Member States shall take the appropriate measures to ensure that the competent authorities referred to in Article 4(3) cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly.

2. The Commission shall provide for the organisation of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive.

Article 20

Legal remedies

Any measure taken pursuant to this Directive which restricts the placing on the market and/or putting into service of any machinery covered by this Directive shall state the exact grounds on which it is based. Such a measure shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time limits to which such remedies are subject.

2. Where reference is made to this pa
and 7 of Decision 1999/468/EC shall app
the provisions of Article 8 thereof.

3. Where reference is made to this parag
7 of Decision 1999/468/EC shall apply, h
provisions of Article 8 thereof.

The period laid down in Article 5(6) of De
shall be set at three months.

4. The Committee shall adopt its rules of

Article 23

Penalties

Member States shall lay down the rules on
to infringements of the national provision
to this Directive and shall take all measures
that they are implemented. The penalties p
effective, proportionate and dissuasive. M
notify those provisions to the Commissio
and shall notify it without delay of any sub
affecting them.

Article 24

Amendment of Directive 95

Directive 95/16/EC is hereby amended as fo

1. in Article 1, paragraphs 2 and 3 shall
following:

2. 'For the purposes of this Directive
lifting appliance serving specific level
moving along guides which are rigid
angle of more than 15 degrees to the
for the transport of

— persons,

— persons and goods

— cableways, including funicular railways,

— lifts specially designed and constructed for military or police purposes,

— lifting appliances from which work can be carried out,

— mine winding gear,

— lifting appliances intended for lifting performers during artistic performances,

— lifting appliances fitted in means of transport,

— lifting appliances connected to machinery and intended exclusively for access to workstations including maintenance and inspection points on the machinery,

— rack and pinion trains,

— escalators and mechanical walkways.';

2. in Annex I, point 1.2 shall be replaced by the following:

1.2. 'Carrier

The carrier of each lift must be a car. This car must be designed and constructed to offer the space and strength corresponding to the maximum number of persons and the rated load of the lift set by the installer.

Where the lift is intended for the transport of persons, and where its dimensions permit, the car must be designed and constructed in such a way that its structural features do not obstruct or impede access and use by disabled persons and so as to allow any appropriate adjustments intended to facilitate its use by them.'

Article 25

Repeal

Directive 98/37/EC is hereby repealed.

References made to the repealed Directive shall be construed as being made to this Directive and should be read in accordance with the correlation table in Annex XII.

December 2009.

When Member States adopt those provisions a reference to this Directive or shall be acc reference on the occasion of their official p States shall determine how such reference is

2. Member States shall communicate to t text of the provisions of national law which field covered by this Directive, together wi how the provisions of this Directive corresp provisions adopted.

Article 27

Derogation

Until 29 June 2011 Member States may all the market and the putting into service of operated fixing and other impact machin conformity with the national provisions in f of this Directive.

Article 28

Entry into force

This Directive shall enter into force on the its publication in the *Official Journal of the Eu*

Article 29

Addressees

This Directive is addressed to the Member St

Done at Strasbourg, 17 May 2006.

For the European Parliament
The President
J. BORRELL FONTELLES

For
Th
H.

out in order to determine the health and safety requirements which apply to the machinery. The mac must then be designed and constructed taking into account the results of the risk assessment.

By the iterative process of risk assessment and risk reduction referred to above, the manufacturer authorised representative shall:

— determine the limits of the machinery, which include the intended use and any reasonably fores misuse thereof,

— identify the hazards that can be generated by the machinery and the associated hazardous situations

— estimate the risks, taking into account the severity of the possible injury or damage to health a probability of its occurrence,

— evaluate the risks, with a view to determining whether risk reduction is required, in accordance wi objective of this Directive,

— eliminate the hazards or reduce the risks associated with these hazards by application of pro measures, in the order of priority established in section 1.1.2(b).

2. The obligations laid down by the essential health and safety requirements only apply when the correspo hazard exists for the machinery in question when it is used under the conditions foreseen by the ma turer or his authorised representative or in foreseeable abnormal situations. In any event, the princi safety integration referred to in section 1.1.2 and the obligations concerning marking of machiner instructions referred to in sections 1.7.3 and 1.7.4 apply.

3. The essential health and safety requirements laid down in this Annex are mandatory; However, takin account the state of the art, it may not be possible to meet the objectives set by them. In that eve machinery must, as far as possible, be designed and constructed with the purpose of approaching these tives.

4. This Annex is organised in several parts. The first one has a general scope and is applicable to all ki machinery. The other parts refer to certain kinds of more specific hazards. Nevertheless, it is essen examine the whole of this Annex in order to be sure of meeting all the relevant essential requirements. machinery is being designed, the requirements of the general part and the requirements of one or more other parts shall be taken into account, depending on the results of the risk assessment carried out in a ance with point 1 of these General Principles.

1. *ESSENTIAL HEALTH AND SAFETY REQUIREMENTS*

1.1. GENERAL REMARKS

1.1.1. ***Definitions***

For the purpose of this Annex:

(a) 'hazard' means a potential source of injury or damage to health;

(b) 'danger zone' means any zone within and/or around machinery in which a person is subject to a his health or safety;

(c) 'exposed person' means any person wholly or partially in a danger zone;

(d) 'operator' means the person or persons installing, operating, adjusting, maintaining, cleaning, repair moving machinery;

(e) 'risk' means a combination of the probability and the degree of an injury or damage to health th arise in a hazardous situation;

(b) In selecting the most appropriate methods, the manufacturer or his authorised representative must ap the following principles, in the order given:

— eliminate or reduce risks as far as possible (inherently safe machinery design and construction),

— take the necessary protective measures in relation to risks that cannot be eliminated,

— inform users of the residual risks due to any shortcomings of the protective measures adopted, in cate whether any particular training is required and specify any need to provide personal protec equipment.

(c) When designing and constructing machinery and when drafting the instructions, the manufacturer or authorised representative must envisage not only the intended use of the machinery but also any reas ably foreseeable misuse thereof.

The machinery must be designed and constructed in such a way as to prevent abnormal use if such would engender a risk. Where appropriate, the instructions must draw the user's attention to ways which experience has shown might occur — in which the machinery should not be used.

(d) Machinery must be designed and constructed to take account of the constraints to which the operato subject as a result of the necessary or foreseeable use of personal protective equipment.

(e) Machinery must be supplied with all the special equipment and accessories essential to enable it to adjusted, maintained and used safely.

1.1.3. *Materials and products*

The materials used to construct machinery or products used or created during its use must not endan persons' safety or health. In particular, where fluids are used, machinery must be designed and constructed prevent risks due to filling, use, recovery or draining.

1.1.4. *Lighting*

Machinery must be supplied with integral lighting suitable for the operations concerned where the abse thereof is likely to cause a risk despite ambient lighting of normal intensity.

Machinery must be designed and constructed so that there is no area of shadow likely to cause nuisance, t there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to lighting.

Internal parts requiring frequent inspection and adjustment, and maintenance areas must be provided w appropriate lighting.

1.1.5. *Design of machinery to facilitate its handling*

Machinery, or each component part thereof, must:

— be capable of being handled and transported safely,

— be packaged or designed so that it can be stored safely and without damage.

During the transportation of the machinery and/or its component parts, there must be no possibility

1.1.6. *Ergonomics*

Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress fac the operator must be reduced to the minimum possible, taking into account ergonomic principles such

— allowing for the variability of the operator's physical dimensions, strength and stamina,

— providing enough space for movements of the parts of the operator's body,

— avoiding a machine-determined work rate,

— avoiding monitoring that requires lengthy concentration,

— adapting the man/machinery interface to the foreseeable characteristics of the operators.

1.1.7. *Operating positions*

The operating position must be designed and constructed in such a way as to avoid any risk due to e gases and/or lack of oxygen.

If the machinery is intended to be used in a hazardous environment presenting risks to the health and of the operator or if the machinery itself gives rise to a hazardous environment, adequate means m provided to ensure that the operator has good working conditions and is protected against any fores hazards.

Where appropriate, the operating position must be fitted with an adequate cabin designed, constructed equipped to fulfil the above requirements. The exit must allow rapid evacuation. Moreover, when appl an emergency exit must be provided in a direction which is different from the usual exit.

1.1.8. *Seating*

Where appropriate and where the working conditions so permit, work stations constituting an integra of the machinery must be designed for the installation of seats.

If the operator is intended to sit during operation and the operating position is an integral part machinery, the seat must be provided with the machinery.

The operator's seat must enable him to maintain a stable position. Furthermore, the seat and its distanc the control devices must be capable of being adapted to the operator.

If the machinery is subject to vibrations, the seat must be designed and constructed in such a way reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. Th mountings must withstand all stresses to which they can be subjected. Where there is no floor benea feet of the operator, footrests covered with a slip-resistant material must be provided.

1.2. CONTROL SYSTEMS

1.2.1. *Safety and reliability of control systems*

— no moving part of the machinery or piece held by the machinery must fall or be ejected,

— automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded,

— the protective devices must remain fully effective or give a stop command,

— the safety-related parts of the control system must apply in a coherent way to the whole of an ass of machinery and/or partly completed machinery.

For cable-less control, an automatic stop must be activated when correct control signals are not rec including loss of communication.

1.2.2. *Control devices*

Control devices must be:

— clearly visible and identifiable, using pictograms where appropriate,

— positioned in such a way as to be safely operated without hesitation or loss of time and without guity,

— designed in such a way that the movement of the control device is consistent with its effect,

— located outside the danger zones, except where necessary for certain control devices such as an emer stop or a teach pendant,

— positioned in such a way that their operation cannot cause additional risk,

— designed or protected in such a way that the desired effect, where a hazard is involved, can o achieved by a deliberate action,

— made in such a way as to withstand foreseeable forces; particular attention must be paid to emer stop devices liable to be subjected to considerable forces.

Where a control device is designed and constructed to perform several different actions, namely where is no one-to-one correspondence, the action to be performed must be clearly displayed and subject to c mation, where necessary.

Control devices must be so arranged that their layout, travel and resistance to operation are compatibl the action to be performed, taking account of ergonomic principles.

Machinery must be fitted with indicators as required for safe operation. The operator must be able t them from the control position.

From each control position, the operator must be able to ensure that no-one is in the danger zones, control system must be designed and constructed in such a way that starting is prevented while someon the danger zone.

If neither of these possibilities is applicable, before the machinery starts, an acoustic and/or visual w signal must be given. The exposed persons must have time to leave the danger zone or prevent the mac starting up.

— when effecting a significant change in the operating conditions.

However, the restarting of the machinery or a change in operating conditions may be effected by volun actuation of a device other than the control device provided for the purpose, on condition that this does lead to a hazardous situation.

For machinery functioning in automatic mode, the starting of the machinery, restarting after a stoppage, change in operating conditions may be possible without intervention, provided this does not lead to a h dous situation.

Where machinery has several starting control devices and the operators can therefore put each othe danger, additional devices must be fitted to rule out such risks. If safety requires that starting and/or stop must be performed in a specific sequence, there must be devices which ensure that these operations performed in the correct order.

1.2.4. *Stopping*

1.2.4.1. Normal stop

Machinery must be fitted with a control device whereby the machinery can be brought safely to a comp stop.

Each workstation must be fitted with a control device to stop some or all of the functions of the machi depending on the existing hazards, so that the machinery is rendered safe.

The machinery's stop control must have priority over the start controls.

Once the machinery or its hazardous functions have stopped, the energy supply to the actuators conce must be cut off.

1.2.4.2. Operational stop

Where, for operational reasons, a stop control that does not cut off the energy supply to the actuato required, the stop condition must be monitored and maintained.

1.2.4.3. Emergency stop

Machinery must be fitted with one or more emergency stop devices to enable actual or impending dange be averted.

The following exceptions apply:

— machinery in which an emergency stop device would not lessen the risk, either because it would reduce the stopping time or because it would not enable the special measures required to deal with risk to be taken.

Emergency stop devices must be a back-up to other safeguarding measures and not a substitute for th

1.2.4.4. **Assembly of machinery**

In the case of machinery or parts of machinery designed to work together, the machinery must be
and constructed in such a way that the stop controls, including the emergency stop devices, can s
only the machinery itself but also all related equipment, if its continued operation may be dangerous.

1.2.5. *Selection of control or operating modes*

The control or operating mode selected must override all other control or operating modes, with th
tion of the emergency stop.

If machinery has been designed and constructed to allow its use in several control or operating
requiring different protective measures and/or work procedures, it must be fitted with a mode selecto
can be locked in each position. Each position of the selector must be clearly identifiable and must cor
to a single operating or control mode.

The selector may be replaced by another selection method which restricts the use of certain function
machinery to certain categories of operator.

If, for certain operations, the machinery must be able to operate with a guard displaced or removed
protective device disabled, the control or operating mode selector must simultaneously:

— disable all other control or operating modes,

— permit operation of hazardous functions only by control devices requiring sustained action,

— permit the operation of hazardous functions only in reduced risk conditions while preventing
from linked sequences,

— prevent any operation of hazardous functions by voluntary or involuntary action on the m
sensors.

If these four conditions cannot be fulfilled simultaneously, the control or operating mode selector m
vate other protective measures designed and constructed to ensure a safe intervention zone.

In addition, the operator must be able to control operation of the parts he is working on from the adj
point.

1.2.6. *Failure of the power supply*

The interruption, the re-establishment after an interruption or the fluctuation in whatever manne

1.3.1. *Risk of loss of stability*

Machinery and its components and fittings must be stable enough to avoid overturning, falling o trolled movements during transportation, assembly, dismantling and any other action involv machinery.

If the shape of the machinery itself or its intended installation does not offer sufficient stability, ap means of anchorage must be incorporated and indicated in the instructions.

1.3.2. *Risk of break-up during operation*

The various parts of machinery and their linkages must be able to withstand the stresses to which subject when used.

The durability of the materials used must be adequate for the nature of the working environment for the manufacturer or his authorised representative, in particular as regards the phenomena of fatigue corrosion and abrasion.

The instructions must indicate the type and frequency of inspections and maintenance required f reasons. They must, where appropriate, indicate the parts subject to wear and the criteria for replacem

Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned mounted, positioned and/or guarded in such a way that any fragments will be contained, preventin dous situations.

Both rigid and flexible pipes carrying fluids, particularly those under high pressure, must be able to w the foreseen internal and external stresses and must be firmly attached and/or protected to ensure tha is posed by a rupture.

Where the material to be processed is fed to the tool automatically, the following conditions must be to avoid risks to persons:

— when the workpiece comes into contact with the tool, the latter must have attained its normal condition,

— when the tool starts and/or stops (intentionally or accidentally), the feed movement and the too ment must be coordinated.

1.3.3. *Risks due to falling or ejected objects*

Precautions must be taken to prevent risks from falling or ejected objects.

1.3.4. *Risks due to surfaces, edges or angles*

Insofar as their purpose allows, accessible parts of the machinery must have no sharp edges, no shar and no rough surfaces likely to cause injury.

1.3.5. *Risks related to combined machinery*

Where the machinery is intended to carry out several different operations with manual removal of t between each operation (combined machinery), it must be designed and constructed in such a w enable each element to be used separately without the other elements constituting a risk for exposed

The instructions and, where possible, a sign on the machinery shall identify these specific protective
and how they are to be used.

1.3.8. *Choice of protection against risks arising from moving parts*

Guards or protective devices designed to protect against risks arising from moving parts must be sele
the basis of the type of risk. The following guidelines must be used to help to make the choice.

1.3.8.1. **Moving transmission parts**

Guards designed to protect persons against the hazards generated by moving transmission parts must b

— either fixed guards as referred to in section 1.4.2.1, or

— interlocking movable guards as referred to in section 1.4.2.2.

Interlocking movable guards should be used where frequent access is envisaged.

1.3.8.2. **Moving parts involved in the process**

Guards or protective devices designed to protect persons against the hazards generated by movin
involved in the process must be:

— either fixed guards as referred to in section 1.4.2.1, or

— interlocking movable guards as referred to in section 1.4.2.2, or

— protective devices as referred to in section 1.4.3, or

— a combination of the above.

However, when certain moving parts directly involved in the process cannot be made completely inac
during operation owing to operations requiring operator intervention, such parts must be fitted with:

— fixed guards or interlocking movable guards preventing access to those sections of the parts that
used in the work, and

— adjustable guards as referred to in section 1.4.2.3 restricting access to those sections of the movin
where access is necessary.

1.3.9. *Risks of uncontrolled movements*

When a part of the machinery has been stopped, any drift away from the stopping position, for w
reason other than action on the control devices, must be prevented or must be such that it does not pr
hazard.

1.4. REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES

In addition, guards must, where possible, protect against the ejection or falling of materials or obje
against emissions generated by the machinery.

1.4.2. *Special requirements for guards*

1.4.2.1. **Fixed guards**

Fixed guards must be fixed by systems that can be opened or removed only with tools.

Their fixing systems must remain attached to the guards or to the machinery when the guards are rem

Where possible, guards must be incapable of remaining in place without their fixings.

1.4.2.2. **Interlocking movable guards**

Interlocking movable guards must:

— as far as possible remain attached to the machinery when open,

— be designed and constructed in such a way that they can be adjusted only by means of an inte
action.

Interlocking movable guards must be associated with an interlocking device that:

— prevents the start of hazardous machinery functions until they are closed and

— gives a stop command whenever they are no longer closed.

Where it is possible for an operator to reach the danger zone before the risk due to the hazardous ma
functions has ceased, movable guards must be associated with a guard locking device in addition to a
locking device that:

— prevents the start of hazardous machinery functions until the guard is closed and locked, and

— keeps the guard closed and locked until the risk of injury from the hazardous machinery functi
ceased.

Interlocking movable guards must be designed in such a way that the absence or failure of one
components prevents starting or stops the hazardous machinery functions.

1.4.2.3. **Adjustable guards restricting access**

Adjustable guards restricting access to those areas of the moving parts strictly necessary for the wor
be:

1.5.1. *Electricity supply*

Where machinery has an electricity supply, it must be designed, constructed and equipped in such a way
all hazards of an electrical nature are or can be prevented.

The safety objectives set out in Directive 73/23/EEC shall apply to machinery. However, the obliga
concerning conformity assessment and the placing on the market and/or putting into service of mach
with regard to electrical hazards are governed solely by this Directive.

1.5.2. *Static electricity*

Machinery must be designed and constructed to prevent or limit the build-up of potentially dangerous el
static charges and/or be fitted with a discharging system.

1.5.3. *Energy supply other than electricity*

Where machinery is powered by source of energy other than electricity, it must be so designed, constr
and equipped as to avoid all potential risks associated with such sources of energy.

1.5.4. *Errors of fitting*

Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be
impossible by the design and construction of such parts or, failing this, by information given on the
themselves and/or their housings. The same information must be given on moving parts and/or their hou
where the direction of movement needs to be known in order to avoid a risk.

Where necessary, the instructions must give further information on these risks.

Where a faulty connection can be the source of risk, incorrect connections must be made impossib
design or, failing this, by information given on the elements to be connected and, where appropriate, o
means of connection.

1.5.5. *Extreme temperatures*

Steps must be taken to eliminate any risk of injury arising from contact with or proximity to machinery
or materials at high or very low temperatures.

The necessary steps must also be taken to avoid or protect against the risk of hot or very cold material
ejected.

1.5.6. *Fire*

Machinery must be designed and constructed in such a way as to avoid any risk of fire or overheating
by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used b
machinery.

1.5.9. *Vibrations*

Machinery must be designed and constructed in such a way that risks resulting from vibrations prod the machinery are reduced to the lowest level, taking account of technical progress and the availa means of reducing vibration, in particular at source.

The level of vibration emission may be assessed with reference to comparative emission data for machinery.

1.5.10. *Radiation*

Undesirable radiation emissions from the machinery must be eliminated or be reduced to levels that have adverse effects on persons.

Any functional ionising radiation emissions must be limited to the lowest level which is sufficient proper functioning of the machinery during setting, operation and cleaning. Where a risk exists, the n protective measures must be taken.

Any functional non-ionising radiation emissions during setting, operation and cleaning must be lir levels that do not have adverse effects on persons.

1.5.11. *External radiation*

Machinery must be designed and constructed in such a way that external radiation does not interfere operation.

1.5.12. *Laser radiation*

Where laser equipment is used, the following should be taken into account:

— laser equipment on machinery must be designed and constructed in such a way as to prevent a dental radiation,

— laser equipment on machinery must be protected in such a way that effective radiation, r produced by reflection or diffusion and secondary radiation do not damage health,

— optical equipment for the observation or adjustment of laser equipment on machinery must be s no health risk is created by laser radiation.

1.5.13. *Emissions of hazardous materials and substances*

Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, cont the skin, eyes and mucous membranes and penetration through the skin of hazardous materi substances which it produces can be avoided.

Where a hazard cannot be eliminated, the machinery must be so equipped that hazardous mater substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another effective method.

1.5.16. *Lightning*

Machinery in need of protection against the effects of lightning while being used must be fitted with for conducting the resultant electrical charge to earth.

1.6. MAINTENANCE

1.6.1. *Machinery maintenance*

Adjustment and maintenance points must be located outside danger zones. It must be possible to adjustment, maintenance, repair, cleaning and servicing operations while machinery is at a standstill.

If one or more of the above conditions cannot be satisfied for technical reasons, measures must be ensure that these operations can be carried out safely (see section 1.2.5).

In the case of automated machinery and, where necessary, other machinery, a connecting device for diagnostic fault-finding equipment must be provided.

Automated machinery components which have to be changed frequently must be capable of being and replaced easily and safely. Access to the components must enable these tasks to be carried out necessary technical means in accordance with a specified operating method.

1.6.2. *Access to operating positions and servicing points*

Machinery must be designed and constructed in such a way as to allow access in safety to all are intervention is necessary during operation, adjustment and maintenance of the machinery.

1.6.3. *Isolation of energy sources*

Machinery must be fitted with means to isolate it from all energy sources. Such isolators must be cle tified. They must be capable of being locked if reconnection could endanger persons. Isolators mu capable of being locked where an operator is unable, from any of the points to which he has access, that the energy is still cut off.

In the case of machinery capable of being plugged into an electricity supply, removal of the plug is provided that the operator can check from any of the points to which he has access that the plug removed.

After the energy is cut off, it must be possible to dissipate normally any energy remaining or stor circuits of the machinery without risk to persons.

As an exception to the requirement laid down in the previous paragraphs, certain circuits ma connected to their energy sources in order, for example, to hold parts, to protect information, to li iors, etc. In this case, special steps must be taken to ensure operator safety.

1.6.4. *Operator intervention*

1.7.1.1. **Information and information devices**

The information needed to control machinery must be provided in a form that is unambiguous a understood. It must not be excessive to the extent of overloading the operator.

Visual display units or any other interactive means of communication between the operator and the must be easily understood and easy to use.

1.7.1.2. **Warning devices**

Where the health and safety of persons may be endangered by a fault in the operation of unsu machinery, the machinery must be equipped in such a way as to give an appropriate acoustic or lig as a warning.

Where machinery is equipped with warning devices these must be unambiguous and easily perce operator must have facilities to check the operation of such warning devices at all times.

The requirements of the specific Community Directives concerning colours and safety signals complied with.

1.7.2. ***Warning of residual risks***

Where risks remain despite the inherent safe design measures, safeguarding and complementary p measures adopted, the necessary warnings, including warning devices, must be provided.

1.7.3. ***Marking of machinery***

All machinery must be marked visibly, legibly and indelibly with the following minimum particulars:

— the business name and full address of the manufacturer and, where applicable, his authorised re tive,

— designation of the machinery,

— the CE Marking (see Annex III),

— designation of series or type,

— serial number, if any,

— the year of construction, that is the year in which the manufacturing process is completed.

It is prohibited to pre-date or post-date the machinery when affixing the CE marking.

Furthermore, machinery designed and constructed for use in a potentially explosive atmosphere marked accordingly.

Machinery must also bear full information relevant to its type and essential for safe use. Such infor subject to the requirements set out in section 1.7.1.

Where a machine part must be handled during use with lifting equipment, its mass must be indicate

(a) The instructions must be drafted in one or more official Community languages. The words instructions' must appear on the language version(s) verified by the manufacturer or his authorise sentative.

(b) Where no 'Original instructions' exist in the official language(s) of the country where the machin be used, a translation into that/those language(s) must be provided by the manufacturer or his au representative or by the person bringing the machinery into the language area in question. The tions must bear the words 'Translation of the original instructions'.

(c) The contents of the instructions must cover not only the intended use of the machinery but also account any reasonably foreseeable misuse thereof.

(d) In the case of machinery intended for use by non-professional operators, the wording and layo instructions for use must take into account the level of general education and acumen that can re be expected from such operators.

1.7.4.2. Contents of the instructions

Each instruction manual must contain, where applicable, at least the following information:

(a) the business name and full address of the manufacturer and of his authorised representative;

(b) the designation of the machinery as marked on the machinery itself, except for the serial num section 1.7.3);

(c) the EC declaration of conformity, or a document setting out the contents of the EC declaration o mity, showing the particulars of the machinery, not necessarily including the serial number signature;

(d) a general description of the machinery;

(e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and the machinery and for checking its correct functioning;

(f) a description of the workstation(s) likely to be occupied by operators;

(g) a description of the intended use of the machinery;

(h) warnings concerning ways in which the machinery must not be used that experience has show occur;

(i) assembly, installation and connection instructions, including drawings, diagrams and the means ment and the designation of the chassis or installation on which the machinery is to be mounted

(j) instructions relating to installation and assembly for reducing noise or vibration;

(k) instructions for the putting into service and use of the machinery and, if necessary, instruction training of operators;

(l) information about the residual risks that remain despite the inherent safe design measures, safe and complementary protective measures adopted;

(m) instructions on the protective measures to be taken by the user, including, where appropr personal protective equipment to be provided;

(a) the following information on airborne noise emissions:

— the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); this level does not exceed 70 dB(A), this fact must be indicated,

— the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds (130 dB in relation to 20 μPa),

— the A-weighted sound power level emitted by the machinery, where the A-weighted emission pressure level at workstations exceeds 80 dB(A).

These values must be either those actually measured for the machinery in question or those estab on the basis of measurements taken for technically comparable machinery which is representative machinery to be produced.

In the case of very large machinery, instead of the A-weighted sound power level, the A-weighted sion sound pressure levels at specified positions around the machinery may be indicated.

Where the harmonised standards are not applied, sound levels must be measured using the most a priate method for the machinery. Whenever sound emission values are indicated the uncert surrounding these values must be specified. The operating conditions of the machinery during me ment and the measuring methods used must be described.

Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels m measured at a distance of 1 metre from the surface of the machinery and at a height of 1,6 metres the floor or access platform. The position and value of the maximum sound pressure must be indic

Where specific Community Directives lay down other requirements for the measurement of sound sure levels or sound power levels, those Directives must be applied and the corresponding provisi this section shall not apply;

(v) where machinery is likely to emit non-ionising radiation which may cause harm to persons, in par persons with active or non-active implantable medical devices, information concerning the rad emitted for the operator and exposed persons.

1.7.4.3. Sales literature

Sales literature describing the machinery must not contradict the instructions as regards health and aspects. Sales literature describing the performance characteristics of machinery must contain the same mation on emissions as is contained in the instructions.

2. *SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORI MACHINERY*

Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-g machinery, portable fixing and other impact machinery, machinery for working wood and materia similar physical characteristics must meet all the essential health and safety requirements described i chapter (see General Principles, point 4).

— be smooth and have neither ridges nor crevices which could harbour organic materials. The applies to their joinings,

— be designed and constructed in such a way as to reduce the projections, edges and recesses of a blies to a minimum,

— be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the surfaces must have curves with a radius sufficient to allow thorough cleaning;

(c) it must be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmace products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged fro machinery (if possible, in a 'cleaning' position);

(d) machinery must be designed and constructed in such a way as to prevent any substances or living tures, in particular insects, from entering, or any organic matter from accumulating in, areas that c be cleaned;

(e) machinery must be designed and constructed in such a way that no ancillary substances hazardo health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmace products. Where necessary, machinery must be designed and constructed in such a way that conti compliance with this requirement can be checked.

2.1.2. *Instructions*

The instructions for foodstuffs machinery and machinery for use with cosmetics or pharmaceutical pro must indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for accessible areas but also for areas to which access is impossible or inadvisable.

2.2. PORTABLE HAND-HELD AND/OR HAND-GUIDED MACHINERY

2.2.1. *General*

Portable hand-held and/or hand-guided machinery must:

— depending on the type of machinery, have a supporting surface of sufficient size and have a suf number of handles and supports of an appropriate size, arranged in such a way as to ensure the st of the machinery under the intended operating conditions,

— except where technically impossible, or where there is an independent control device, in the ca handles which cannot be released in complete safety, be fitted with manual start and stop control d arranged in such a way that the operator can operate them without releasing the handles,

— present no risks of accidental starting and/or continued operation after the operator has release handles. Equivalent steps must be taken if this requirement is not technically feasible,

— permit, where necessary, visual observation of the danger zone and of the action of the tool wit material being processed.

The handles of portable machinery must be designed and constructed in such a way as to make startin stopping straightforward.

the harmonised standard applied, must be specified.

2.2.2. *Portable fixing and other impact machinery*

2.2.2.1. General

Portable fixing and other impact machinery must be designed and constructed in such a way that:

— energy is transmitted to the impacted element by the intermediary component that does not lea device,

— an enabling device prevents impact unless the machinery is positioned correctly with adequate p on the base material,

— involuntary triggering is prevented; where necessary, an appropriate sequence of actions on the en device and the control device must be required to trigger an impact,

— accidental triggering is prevented during handling or in case of shock,

— loading and unloading operations can be carried out easily and safely.

Where necessary, it must be possible to fit the device with splinter guard(s) and the appropriate guard(s be provided by the manufacturer of the machinery.

2.2.2.2. Instructions

The instructions must give the necessary information regarding:

— the accessories and interchangeable equipment that can be used with the machinery,

— the suitable fixing or other impacted elements to be used with the machinery,

— where appropriate, the suitable cartridges to be used.

2.3. MACHINERY FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTIC

Machinery for working wood and materials with similar physical characteristics must comply wi following requirements:

(a) the machinery must be designed, constructed or equipped in such a way that the piece being ma can be placed and guided in safety; where the piece is hand-held on a work-bench, the latter m sufficiently stable during the work and must not impede the movement of the piece;

(b) where the machinery is likely to be used in conditions involving the risk of ejection of workpie parts of them, it must be designed, constructed, or equipped in such a way as to prevent such ej or, if this is not possible, so that the ejection does not engender risks for the operator and/or e persons;

(c) the machinery must be equipped with an automatic brake that stops the tool in a sufficiently short there is a risk of contact with the tool whilst it runs down;

— machinery which is operated without being moved, but which may be equipped in such a way enable it to be moved more easily from one place to another.

(b) 'Driver' means an operator responsible for the movement of a machine. The driver may be transpor the machinery or may be on foot, accompanying the machinery, or may guide the machinery by r control.

3.2. WORK POSITIONS

3.2.1. *Driving position*

Visibility from the driving position must be such that the driver can, in complete safety for himself a exposed persons, operate the machinery and its tools in their foreseeable conditions of use. Where nec appropriate devices must be provided to remedy hazards due to inadequate direct vision.

Machinery on which the driver is transported must be designed and constructed in such a way that, fro driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks.

The driving position of ride-on drivers must be designed and constructed in such a way that a drive may be fitted provided this does not increase the risk and there is room for it. The cab must incorpo place for the instructions needed for the driver.

3.2.2. *Seating*

Where there is a risk that operators or other persons transported by the machinery may be crushed be parts of the machinery and the ground should the machinery roll or tip over, in particular for mac equipped with a protective structure referred to in section 3.4.3 or 3.4.4, their seats must be desig equipped with a restraint system so as to keep the persons in their seats, without restricting move necessary for operations or movements relative to the structure caused by the suspension of the seats restraint systems should not be fitted if they increase the risk.

3.2.3. *Positions for other persons*

If the conditions of use provide that persons other than the driver may occasionally or regularly be ported by the machinery or work on it, appropriate positions must be provided which enable them transported or to work on it without risk.

The second and third paragraphs of section 3.2.1 also apply to the places provided for persons other th driver.

3.3. CONTROL SYSTEMS

If necessary, steps must be taken to prevent unauthorised use of controls.

In the case of remote controls each control unit must clearly identify the machinery to be controlle

clean.

Where their operation can lead to hazards, notably dangerous movements, the control devices, those with preset positions, must return to the neutral position as soon as they are released by the

In the case of wheeled machinery, the steering system must be designed and constructed in such a reduce the force of sudden movements of the steering wheel or the steering lever caused by sho guide wheels.

Any control that locks the differential must be so designed and arranged that it allows the differe unlocked when the machinery is moving.

The sixth paragraph of section 1.2.2, concerning acoustic and/or visual warning signals, applies case of reversing.

3.3.2. *Starting/moving*

All travel movements of self-propelled machinery with a ride-on driver must be possible only if th at the controls.

Where, for operating purposes, machinery is fitted with devices which exceed its normal clearance stabilisers, jib, etc.), the driver must be provided with the means of checking easily, before m machinery, that such devices are in a particular position which allows safe movement.

This also applies to all other parts which, to allow safe movement, have to be in particular position necessary.

Where it does not give rise to other risks, movement of the machinery must depend on safe pos the aforementioned parts.

It must not be possible for unintentional movement of the machinery to occur while the engi started.

3.3.3. *Travelling function*

Without prejudice to road traffic regulations, self-propelled machinery and its trailers must meet t ments for slowing down, stopping, braking and immobilisation so as to ensure safety under all the load, speed, ground and gradient conditions allowed for.

The driver must be able to slow down and stop self-propelled machinery by means of a main dev safety so requires, in the event of a failure of the main device, or in the absence of the energy sup to actuate the main device, an emergency device with a fully independent and easily accessible con must be provided for slowing down and stopping.

Where safety so requires, a parking device must be provided to render stationary machinery imm device may be combined with one of the devices referred to in the second paragraph, provided purely mechanical.

Remote-controlled machinery must be equipped with devices for stopping operation automatically

— injury from rotating tools.

The speed of travel of the machinery must be compatible with the pace of a driver on foot.

In the case of machinery on which a rotary tool may be fitted, it must not be possible to actuate when the reverse control is engaged, except where the movement of the machinery results from mov the tool. In the latter case, the reversing speed must be such that it does not endanger the driver.

3.3.5. *Control circuit failure*

A failure in the power supply to the power-assisted steering, where fitted, must not prevent machin being steered during the time required to stop it.

3.4. PROTECTION AGAINST MECHANICAL HAZARDS

3.4.1. *Uncontrolled movements*

Machinery must be designed, constructed and where appropriate placed on its mobile support in suc as to ensure that, when moved, uncontrolled oscillations of its centre of gravity do not affect its sta exert excessive strain on its structure.

3.4.2. *Moving transmission parts*

By way of exception to section 1.3.8.1, in the case of engines, moveable guards preventing acce moving parts in the engine compartment need not have interlocking devices if they have to be open by the use of a tool or key or by a control located in the driving position, providing the latter is i enclosed cab with a lock to prevent unauthorised access.

3.4.3. *Roll-over and tip-over*

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), t risk of rolling or tipping over, the machinery must be fitted with an appropriate protective structur this increases the risk.

This structure must be such that in the event of rolling or tipping over it affords the ride-on pers adequate deflection-limiting volume.

In order to verify that the structure complies with the requirement laid down in the second paragr manufacturer or his authorised representative must, for each type of structure concerned, perform ap tests or have such tests performed.

3.4.4. *Falling objects*

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), t risk due to falling objects or material, the machinery must be designed and constructed in such a w take account of this risk and fitted, if its size allows, with an appropriate protective structure.

This structure must be such that, in the event of falling objects or material, it guarantees the ride-on an adequate deflection-limiting volume.

3.4.7. *Transmission of power between self-propelled machinery (or tractor) and recipient machinery*

Removable mechanical transmission devices linking self-propelled machinery (or a tractor) to the bearing of recipient machinery must be designed and constructed in such a way that any part th during operation is protected over its whole length.

On the side of the self-propelled machinery (or tractor), the power take-off to which the removabl ical transmission device is attached must be protected either by a guard fixed and linked to the self machinery (or tractor) or by any other device offering equivalent protection.

It must be possible to open this guard for access to the removable transmission device. Once it i there must be enough room to prevent the drive shaft damaging the guard when the machine tractor) is moving.

On the recipient machinery side, the input shaft must be enclosed in a protective casing fix machinery.

Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adj driven machinery. The removable mechanical transmission device must be marked accordingly.

All recipient machinery, the operation of which requires a removable mechanical transmission connect it to self-propelled machinery (or a tractor) must have a system for attaching the removabl ical transmission device so that, when the machinery is uncoupled, the removable mechanical tra device and its guard are not damaged by contact with the ground or part of the machinery.

The outside parts of the guard must be so designed, constructed and arranged that they cannot turn removable mechanical transmission device. The guard must cover the transmission to the ends of jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in t wide-angle universal joints.

If means of access to working positions are provided near to the removable mechanical transmissi they must be designed and constructed in such a way that the shaft guards cannot be used as ste designed and constructed for that purpose.

3.5. PROTECTION AGAINST OTHER HAZARDS

3.5.1. *Batteries*

The battery housing must be designed and constructed in such a way as to prevent the electro ejected on to the operator in the event of rollover or tipover and to avoid the accumulation of v places occupied by operators.

Machinery must be designed and constructed in such a way that the battery can be disconnected w of an easily accessible device provided for that purpose.

3.5.2. *Fire*

Depending on the hazards anticipated by the manufacturer, machinery must, where its size permits:

Without prejudice to the provisions of road traffic regulations, machinery with a ride-on driver must following equipment:

— an acoustic warning device to alert persons,

— a system of light signals relevant to the intended conditions of use; the latter requirement does n to machinery intended solely for underground working and having no electrical power,

— where necessary, there must be an appropriate connection between a trailer and the machiner operation of signals.

Remote-controlled machinery which, under normal conditions of use, exposes persons to the risk o or crushing must be fitted with appropriate means to signal its movements or with means to protec against such risks. The same applies to machinery which involves, when in use, the constant repeti forward and backward movement on a single axis where the area to the rear of the machine is no visible to the driver.

Machinery must be constructed in such a way that the warning and signalling devices cannot be unintentionally. Where it is essential for safety, such devices must be provided with the means to d they are in good working order and their failure must be made apparent to the operator.

Where the movement of machinery or its tools is particularly hazardous, signs on the machinery provided to warn against approaching the machinery while it is working; the signs must be legible a cient distance to ensure the safety of persons who have to be in the vicinity.

3.6.2. *Marking*

The following must be shown legibly and indelibly on all machinery:

— nominal power expressed in kilowatts (kW),

— mass of the most usual configuration, in kilograms (kg):

and, where appropriate:

— maximum drawbar pull provided for at the coupling hook, in Newtons (N),

— maximum vertical load provided for on the coupling hook, in Newtons (N).

3.6.3. *Instructions*

3.6.3.1. Vibrations

The instructions must give the following information concerning vibrations transmitted by the mac the hand-arm system or to the whole body:

— the vibration total value to which the hand-arm system is subjected if it exceeds 2,5 m/s². W

The instructions for machinery allowing several uses depending on the equipment used and the in for the interchangeable equipment must contain the information necessary for safe assembly and u basic machinery and the interchangeable equipment that can be fitted.

4. *SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS LIFTING OPERATIONS*

Machinery presenting hazards due to lifting operations must meet all the relevant essential health a requirements described in this chapter (see General Principles, point 4).

4.1. GENERAL

4.1.1. *Definitions*

(a) 'Lifting operation' means a movement of unit loads consisting of goods and/or persons necessita given moment, a change of level.

(b) 'Guided load' means a load where the total movement is made along rigid or flexible guides wh tion is determined by fixed points.

(c) 'Working coefficient' means the arithmetic ratio between the load guaranteed by the manufactu authorised representative up to which a component is able to hold it and the maximum wor marked on the component.

(d) 'Test coefficient' means the arithmetic ratio between the load used to carry out the static or dyn on lifting machinery or a lifting accessory and the maximum working load marked on t machinery or lifting accessory.

(e) 'Static test' means the test during which lifting machinery or a lifting accessory is first inspe subjected to a force corresponding to the maximum working load multiplied by the appropriate coefficient and then re-inspected once the said load has been released to ensure that no da occurred.

(f) 'Dynamic test' means the test during which lifting machinery is operated in all its possible conf at the maximum working load multiplied by the appropriate dynamic test coefficient with acco taken of the dynamic behaviour of the lifting machinery in order to check that it functions prope

(g) 'Carrier' means a part of the machinery on or in which persons and/or goods are supported in o lifted.

4.1.2. *Protection against mechanical hazards*

4.1.2.1. Risks due to lack of stability

Machinery must be designed and constructed in such a way that the stability required by section maintained both in service and out of service, including all stages of transportation, assembly and dis during foreseeable component failures and also during the tests carried out in accordance with the in handbook. To that end, the manufacturer or his authorised representative must use the appropriate tion methods.

fatigue and wear, taking due account of their intended use.

The materials used must be chosen on the basis of the intended working environments, with particular r to corrosion, abrasion, impacts, extreme temperatures, fatigue, brittleness and ageing.

Machinery and lifting accessories must be designed and constructed in such a way as to withstand the load in the static tests without permanent deformation or patent defect. Strength calculations mus account of the value of the static test coefficient chosen to guarantee an adequate level of safety. That cient has, as a general rule, the following values:

(a) manually-operated machinery and lifting accessories: 1,5;

(b) other machinery: 1,25.

Machinery must be designed and constructed in such a way as to undergo, without failure, the dynami carried out using the maximum working load multiplied by the dynamic test coefficient. This dynam coefficient is chosen so as to guarantee an adequate level of safety: the coefficient is, as a general rule, to 1,1. As a general rule, the tests will be performed at the nominal speeds provided for. Should the c circuit of the machinery allow for a number of simultaneous movements, the tests must be carried out the least favourable conditions, as a general rule by combining the movements concerned.

4.1.2.4. Pulleys, drums, wheels, ropes and chains

Pulleys, drums and wheels must have a diameter commensurate with the size of the ropes or chains which they can be fitted.

Drums and wheels must be designed, constructed and installed in such a way that the ropes or chains which they are equipped can be wound without coming off.

Ropes used directly for lifting or supporting the load must not include any splicing other than at their Splicings are, however, tolerated in installations which are intended by design to be modified reg according to needs of use.

Complete ropes and their endings must have a working coefficient chosen in such a way as to guaran adequate level of safety. As a general rule, this coefficient is equal to 5.

Lifting chains must have a working coefficient chosen in such a way as to guarantee an adequate le safety. As a general rule, this coefficient is equal to 4.

In order to verify that an adequate working coefficient has been attained, the manufacturer or his auth representative must, for each type of chain and rope used directly for lifting the load and for the rope perform the appropriate tests or have such tests performed.

4.1.2.5. Lifting accessories and their components

Lifting accessories and their components must be sized with due regard to fatigue and ageing processes number of operating cycles consistent with their expected life-span as specified in the operating cond for a given application.

a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;

(e) the maximum working load of a multilegged sling is determined on the basis of the working coef of the weakest leg, the number of legs and a reduction factor which depends on the slinging conf tion;

(f) in order to verify that an adequate working coefficient has been attained, the manufacturer authorised representative must, for each type of component referred to in (a), (b), (c) and (d), perfor appropriate tests or have such tests performed.

4.1.2.6. Control of movements

Devices for controlling movements must act in such a way that the machinery on which they are insta kept safe.

(a) Machinery must be designed and constructed or fitted with devices in such a way that the amplitu movement of its components is kept within the specified limits. The operation of such devices where appropriate, be preceded by a warning.

(b) Where several fixed or rail-mounted machines can be manoeuvred simultaneously in the same place risks of collision, such machinery must be designed and constructed in such a way as to make it po to fit systems enabling these risks to be avoided.

(c) Machinery must be designed and constructed in such a way that the loads cannot creep dangerou fall freely and unexpectedly, even in the event of partial or total failure of the power supply or whe operator stops operating the machine.

(d) It must not be possible, under normal operating conditions, to lower the load solely by friction except in the case of machinery whose function requires it to operate in that way.

(e) Holding devices must be designed and constructed in such a way that inadvertent dropping of the lo avoided.

4.1.2.7. Movements of loads during handling

The operating position of machinery must be located in such a way as to ensure the widest possible vi trajectories of the moving parts, in order to avoid possible collisions with persons, equipment or machinery which might be manoeuvring at the same time and liable to constitute a hazard.

Machinery with guided loads must be designed and constructed in such a way as to prevent persons being injured by movement of the load, the carrier or the counterweights, if any.

4.1.2.8. Machinery serving fixed landings

4.1.2.8.1. *Movements of the carrier*

The movement of the carrier of machinery serving fixed landings must be rigidly guided to and at the ings. Scissor systems are also regarded as rigid guidance.

4.1.2.8.4. *Risk due to the load falling off the carrier*

Where there is a risk due to the load falling off the carrier, the machinery must be designed and cons in such a way as to prevent this risk.

4.1.2.8.5. *Landings*

Risks due to contact of persons at landings with the moving carrier or other moving parts must be pre

Where there is a risk due to persons falling into the travel zone when the carrier is not present at th ings, guards must be fitted in order to prevent this risk. Such guards must not open in the direction travel zone. They must be fitted with an interlocking device controlled by the position of the carri prevents:

— hazardous movements of the carrier until the guards are closed and locked,

— hazardous opening of a guard until the carrier has stopped at the corresponding landing.

4.1.3. *Fitness for purpose*

When lifting machinery or lifting accessories are placed on the market or are first put into service, the facturer or his authorised representative must ensure, by taking appropriate measures or having them that the machinery or the lifting accessories which are ready for use — whether manually or power-o — can fulfil their specified functions safely.

The static and dynamic tests referred to in section 4.1.2.3 must be performed on all lifting machinery to be put into service.

Where the machinery cannot be assembled in the manufacturer's premises or in the premises authorised representative, the appropriate measures must be taken at the place of use. Otherwi measures may be taken either in the manufacturer's premises or at the place of use.

4.2. REQUIREMENTS FOR MACHINERY WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT

4.2.1. *Control of movements*

Hold-to-run control devices must be used to control the movements of the machinery or its equi However, for partial or complete movements in which there is no risk of the load or the machinery co the said devices may be replaced by control devices authorising automatic stops at pre-selected po without the operator holding a hold-to-run control device.

4.2.2. *Loading control*

Machinery with a maximum working load of not less than 1 000 kilograms or an overturning moment less than 40 000 Nm must be fitted with devices to warn the driver and prevent dangerous movements event:

(a) the name and address of the manufacturer and, if appropriate, his authorised representative;

(b) a description of the chain or rope which includes:

— its nominal size,

— its construction,

— the material from which it is made, and

— any special metallurgical treatment applied to the material;

(c) the test method used;

(d) the maximum load to which the chain or rope should be subjected in service. A range of value given on the basis of the intended applications.

4.3.2. *Lifting accessories*

Lifting accessories must show the following particulars:

— identification of the material where this information is needed for safe use,

— the maximum working load.

In the case of lifting accessories on which marking is physically impossible, the particulars referred first paragraph must be displayed on a plate or other equivalent means and securely affixed to the ac

The particulars must be legible and located in a place where they are not liable to disappear as a wear or jeopardise the strength of the accessory.

4.3.3. *Lifting machinery*

The maximum working load must be prominently marked on the machinery. This marking must b indelible and in an un-coded form.

Where the maximum working load depends on the configuration of the machinery, each operating must be provided with a load plate indicating, preferably in diagrammatic form or by means of t working load permitted for each configuration.

Machinery intended for lifting goods only, equipped with a carrier which allows access to persons, m a clear and indelible warning prohibiting the lifting of persons. This warning must be visible at ea where access is possible.

4.4. INSTRUCTIONS

4.4.1. *Lifting accessories*

— the reactions at the supports or anchors and, where appropriate, characteristics of the tracks,

— where appropriate, the definition and the means of installation of the ballast;

(b) the contents of the logbook, if the latter is not supplied with the machinery;

(c) advice for use, particularly to offset the lack of direct vision of the load by the operator;

(d) where appropriate, a test report detailing the static and dynamic tests carried out by or for the ma turer or his authorised representative;

(e) for machinery which is not assembled on the premises of the manufacturer in the form in which be used, the necessary instructions for performing the measures referred to in section 4.1.3 befo first put into service.

5. *SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY INTE FOR UNDERGROUND WORK*

Machinery intended for underground work must meet all the essential health and safety requir described in this chapter (see General Principles, point 4).

5.1. RISKS DUE TO LACK OF STABILITY

Powered roof supports must be designed and constructed in such a way as to maintain a given di when moving and not slip before and while they come under load and after the load has been removed must be equipped with anchorages for the top plates of the individual hydraulic props.

5.2. MOVEMENT

Powered roof supports must allow for unhindered movement of persons.

5.3. CONTROL DEVICES

The accelerator and brake controls for movement of machinery running on rails must be hand-op However, enabling devices may be foot-operated.

The control devices of powered roof supports must be designed and positioned in such a way that, displacement operations, operators are sheltered by a support in place. The control devices must be pr against any accidental release.

5.4. STOPPING

Self-propelled machinery running on rails for use in underground work must be equipped with an e device acting on the circuit controlling the movement of the machinery such that movement is stoppe driver is no longer in control of the movement.

5.5. FIRE

Machinery presenting hazards due to the lifting of persons must meet all the relevant essential healt
safety requirements described in this chapter (see General Principles, point 4).

6.1. GENERAL

6.1.1. *Mechanical strength*

The carrier, including any trapdoors, must be designed and constructed in such a way as to offer the
and strength corresponding to the maximum number of persons permitted on the carrier and the maxi
working load.

The working coefficients for components set out in sections 4.1.2.4 and 4.1.2.5 are inadequate for mach
intended for the lifting of persons and must, as a general rule, be doubled. Machinery intended for l
persons or persons and goods must be fitted with a suspension or supporting system for the carrier des
and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk o
carrier falling.

If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or c
are required, each with its own anchorage.

6.1.2. *Loading control for machinery moved by power other than human strength*

The requirements of section 4.2.2 apply regardless of the maximum working load and overturning mo
unless the manufacturer can demonstrate that there is no risk of overloading or overturning.

6.2. CONTROL DEVICES

Where safety requirements do not impose other solutions, the carrier must, as a general rule, be designe
constructed in such a way that persons in the carrier have means of controlling upward and downward m
ments and, if appropriate, other movements of the carrier.

In operation, those control devices must override any other devices controlling the same movement wit
exception of emergency stop devices.

The control devices for these movements must be of the hold-to-run type except where the carrier its
completely enclosed.

6.3. RISKS TO PERSONS IN OR ON THE CARRIER

6.3.1. *Risks due to movements of the carrier*

Machinery for lifting persons must be designed, constructed or equipped in such a way that the acceler
or deceleration of the carrier does not engender risks for persons.

Where there is a risk of objects falling on the carrier and endangering persons, the carrier must be with a protective roof.

6.4. MACHINERY SERVING FIXED LANDINGS

6.4.1. *Risks to persons in or on the carrier*

The carrier must be designed and constructed in such a way as to prevent risks due to contac persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary i fulfil this requirement, the carrier itself must be completely enclosed with doors fitted with an int device that prevents hazardous movements of the carrier unless the doors are closed. The doors mu closed if the carrier stops between landings where there is a risk of falling from the carrier.

The machinery must be designed, constructed and, where necessary, equipped with devices in such to prevent uncontrolled upward or downward movement of the carrier. These devices must be abl the carrier at its maximum working load and at the foreseeable maximum speed.

The stopping action must not cause deceleration harmful to the occupants, whatever the load conditi

6.4.2. *Controls at landings*

Controls, other than those for emergency use, at landings must not initiate movements of the carrier

— the control devices in the carrier are being operated,

— the carrier is not at a landing.

6.4.3. *Access to the carrier*

The guards at the landings and on the carrier must be designed and constructed in such a way as safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and p be lifted.

6.5. MARKINGS

The carrier must bear the information necessary to ensure safety including:

— the number of persons permitted on the carrier,

— the maximum working load.

This declaration and translations thereof must be drawn up under the same conditions as the instruct
Annex I, section 1.7.4.1 (a) and (b)), and must be typewritten or else handwritten in capital letters.

This declaration relates exclusively to the machinery in the state in which it was placed on the market, and
components which are added and/or operations carried out subsequently by the final user.

The EC declaration of conformity must contain the following particulars:

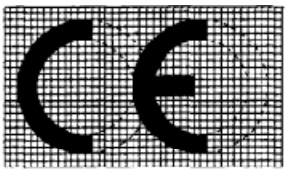
1. business name and full address of the manufacturer and, where appropriate, his authorised representati
2. name and address of the person authorised to compile the technical file, who must be established in t
munity;
3. description and identification of the machinery, including generic denomination, function, model, ty
number and commercial name;
4. a sentence expressly declaring that the machinery fulfils all the relevant provisions of this Directive ar
appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisi
which the machinery complies. These references must be those of the texts published in the *Official*
the European Union;
5. where appropriate, the name, address and identification number of the notified body which carried ou
type-examination referred to in Annex IX and the number of the EC type-examination certificate;
6. where appropriate, the name, address and identification number of the notified body which approved
quality assurance system referred to in Annex X;
7. where appropriate, a reference to the harmonised standards used, as referred to in Article 7(2);
8. where appropriate, the reference to other technical standards and specifications used;
9. the place and date of the declaration;
10. the identity and signature of the person empowered to draw up the declaration on behalf of the man
or his authorised representative.

B. DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY

This declaration and translations thereof must be drawn up under the same conditions as the instruct
Annex 1, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.

The declaration of incorporation must contain the following particulars:

1. business name and full address of the manufacturer of the partly completed machinery and, where app
his authorised representative;
2. name and address of the person authorised to compile the relevant technical documentation, who must
lished in the Community;
3. description and identification of the partly completed machinery including generic denomination,
model, type, serial number and commercial name;
4. a sentence declaring which essential requirements of this Directive are applied and fulfilled and that the
technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a
declaring the conformity of the partly completed machinery with other relevant Directives. These r
must be those of the texts published in the *Official Journal of the European Union*;
5. an undertaking to transmit, in response to a reasoned request by the national authorities, relevant inf



If the CE marking is reduced or enlarged the proportions shown in the above drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be le than 5 mm. The minimum dimension may be waived for small-scale machinery.

The CE marking must be affixed in the immediate vicinity of the name of the manufacturer or his authorised represent tive, using the same technique.

Where the full quality assurance procedure referred to in Article 12(3)(c) and 12(4)(b) has been applied, the CE markin must be followed by the identification number of the notified body.

1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the piece or with a demountable power feed;

1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-be carriage;

1.3 sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the work with manual loading and/or unloading;

1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with m loading and/or unloading.

2. Hand-fed surface planing machinery for woodworking.

3. Thicknessers for one-side dressing having a built-in mechanical feed device with manual loading and/or unl for woodworking.

4. Band-saws with manual loading and/or unloading for working with wood and material with similar physica acteristics or for working with meat and material with similar physical characteristics, of the following types

4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or s for the workpiece;

4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.

5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and m with similar physical characteristics.

6. Hand-fed tenoning machinery with several tool holders for woodworking.

7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical c teristics.

8. Portable chainsaws for woodworking.

9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.

10. Injection or compression plastics-moulding machinery with manual loading or unloading.

11. Injection or compression rubber-moulding machinery with manual loading or unloading.

12. Machinery for underground working of the following types:

12.1. locomotives and brake-vans;

12.2. hydraulic-powered roof supports.

13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.

14. Removable mechanical transmission devices including their guards.

15. Guards for removable mechanical transmission devices.

16. Vehicle servicing lifts.

17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical hei more than three metres.

18. Portable cartridge-operated fixing and other impact machinery.

19. Protective devices designed to detect the presence of persons.

20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred points 9, 10 and 11.

21. Logic units to ensure safety functions.

22. Roll-over protective structures (ROPS).

23. Falling-object protective structures (FOPS).

2. Protective devices designed to detect the presence of persons.
3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in ite 10 and 11 of Annex IV.
4. Logic units to ensure safety functions.
5. Valves with additional means for failure detection intended for the control of dangerous movements on machin
6. Extraction systems for machinery emissions.
7. Guards and protective devices designed to protect persons against moving parts involved in the process or machinery.
8. Monitoring devices for loading and movement control in lifting machinery.
9. Restraint systems to keep persons on their seats.
10. Emergency stop devices.
11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.
12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex I.
13. Systems and devices to reduce the emission of noise and vibrations.
14. Roll-over protective structures (ROPS).
15. Falling-object protective structures (FOPS).
16. Two-hand control devices.
17. Components for machinery designed for lifting and/or lowering persons between different landings and includ the following list:
    (a) devices for locking landing doors;
    (b) devices to prevent the load-carrying unit from falling or unchecked upwards movemen:;
    (c) overspeed limitation devices;
    (d) energy-accumulating shock absorbers
        — non-linear, or
        — with damping of the return movement;
    (e) energy-dissipating shock absorbers;
    (f) safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls;
    (g) electric safety devices in the form of safety switches containing electronic components.

The assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the final machinery, so as not to compromise safety and health.

The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative.

Annex I, section 1.7.4.1 apply.

1. The technical file shall comprise the following:

   (a) a construction file including:

   — a general description of the machinery,

   — the overall drawing of the machinery and drawings of the control circuits, as well as the perti descriptions and explanations necessary for understanding the operation of the machinery,

   — full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., require check the conformity of the machinery with the essential health and safety requirements,

   — the documentation on risk assessment demonstrating the procedure followed, including:

   (i) a list of the essential health and safety requirements which apply to the machinery,

   (ii) the description of the protective measures implemented to eliminate identified hazards or to re risks and, when appropriate, the indication of the residual risks associated with the machinery,

   — the standards and other technical specifications used, indicating the essential health and safety req ments covered by these standards,

   — any technical report giving the results of the tests carried out either by the manufacturer or by a l chosen by the manufacturer or his authorised representative,

   — a copy of the instructions for the machinery,

   — where appropriate, the declaration of incorporation for included partly completed machinery and relevant assembly instructions for such machinery,

   — where appropriate, copies of the EC declaration of conformity of machinery or other products inco rated into the machinery,

   — a copy of the EC declaration of conformity;

   (b) for series manufacture, the internal measures that will be implemented to ensure that the machinery rem in conformity with the provisions of this Directive.

   The manufacturer must carry out necessary research and tests on components, fittings or the comp machinery to determine whether by its design or construction it is capable of being assembled and put service safely. The relevant reports and results shall be included in the technical file.

2. The technical file referred to in point 1 must be made available to the competent authorities of the Mer States for at least 10 years following the date of manufacture of the machinery or, in the case of series manu ture, of the last unit produced.

   The technical file does not have to be located in the territory of the Community, nor does it have to be pe nently available in material form. However, it must be capable of being assembled and made available with

It shall comprise the following:

(a) a construction file including:

— the overal drawing of the partly completed machinery and drawings of the control circuits,

— full detailed drawings, accompanied by any calculation notes, test results, certificates etc., required to che the conformity of the partly completed machinery with the applied essential health and safety requirement

— the risk assessment documentation showing the procedure followed, including:

(i) a list of the essential health and safety requirements applied and fulfilled,

(ii) the description of the protective measures implemented to eliminate identified hazards or to redu risks and, where appropriate, the indication of the residual risks,

(iii) the standards and other technical specifications used, indicating the essential health and safety requir ments covered by these standards,

(iv) any technical report giving the results of the tests carried out either by the manufacturer or by a bo chosen by the manufacturer or his authorised representative,

(v) a copy of the assembly instructions for the partly completed machinery;

(b) for series manufacture, the internal measures that will be implemented to ensure that the partly complet machinery remains in conformity with the essential health and safety requirements applied.

The manufacturer must carry out necessary research and tests on components, fittings or the partly complet machinery to determine whether by its design or construction it is capable of being assembled and used safely. T relevant reports and results shall be included in the technical file.

The relevant technical documentation must be available for at leas 10 years following the date of manufacture the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on requ presented to the competent authorities of the Member States. It does not have to be located in the territory of t Community, nor does it have to be permanently available in material form. It must be capable of being assembl and presented to the relevant authority by the person designated in the declaration for incorporation.

Failure to present the relevant technical documentation in response to a duly reasoned request by the compete national authorities may constitute sufficient grounds for doubting the conformity of the partly complet machinery with the essential health and safety requirements applied and attested.

obligations laid down in points 2 and 3, ensures and declares that the machinery concerned satisfies the relevant requirements of this Directive.

2. For each representative type of the series in question, the manufacturer or his authorised representative shall draw up the technical file referred to in Annex VII, part A.

3. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured machinery with the technical file referred to in Annex VII, part A, and with the requirements of this Directive.

1. The manufacturer or his authorised representative must, for each type, draw up the technical file referred
Annex VII, part A.

2. For each type, the application for an EC type-examination shall be submitted by the manufacturer or his autho
representative to a notified body of his choice.

The application shall include:

— the name and address of the manufacturer and, where appropriate, his authorised representative,

— a written declaration that the application has not been submitted to another notified body,

— the technical file.

Moreover, the applicant shall place at the disposal of the notified body a sample of the type. The notified body
ask for further samples if the test programme so requires.

3. The notified body shall:

3.1. examine the technical file, check that the type was manufactured in accordance with it and establish w
elements have been designed in accordance with the relevant provisions of the standards referred to in Article
and those elements whose design is not based on the relevant provisions of those standards;

3.2. carry out or have carried out appropriate inspections, measurements and tests to ascertain whether the solu
adopted satisfy the essential health and safety requirements of this Directive, where the standards referred
Article 7 (2) were not applied;

3.3. where harmonised standards referred to in Article 7(2) were used, carry out or have carried out appropriate in
tions, measurements and tests to verify that those standards were actually applied;

3.4. agree with the applicant as to the place where the check that the type was manufactured in accordance wit
examined technical file and the necessary inspections, measurements and tests will be carried out.

4. If the type satisfies the provisions of this Directive, the notified body shall issue the applicant with an EC
examination certificate. The certificate shall include the name and address of the manufacturer and his autho
representative, the data necessary for identifying the approved type, the conclusions of the examination and
conditions to which its issue may be subject.

The manufacturer and the notified body shall retain a copy of this certificate, the technical file and all rel
documents for a period of 15 years from the date of issue of the certificate.

5. If the type does not satisfy the provisions of this Directive, the notified body shall refuse to issue the applicant
an EC type-examination certificate, giving detailed reasons for its refusal. It shall inform the applicant, the
notified bodies and the Member State which notified it. An appeal procedure must be available.

6. The applicant shall inform the notified body which retains the technical file relating to the EC type-examin
certificate of all modifications to the approved type. The notified body shall examine these modifications and
then either confirm the validity of the existing EC type-examination certificate or issue a new one if the mod

9.3. The manufacturer shall request from the notified body the review of the validity of the EC type-examination cert
cate every five years.

If the notified body finds that the certificate remains valid, taking into account the state of the art, it shall ren
the certificate for a further five years.

The manufacturer and the notified body shall retain a copy of this certificate, of the technical file and of all the re
vant documents for a period of 15 years from the date of issue of the certificate.

9.4. In the event that the validity of the EC-type examination certificate is not renewed, the manufacturer shall cease
placing on the market of the machinery concerned.

1. The manufacturer must operate an approved quality system for design, manufacture, final inspection and testi specified in point 2, and shall be subject to the surveillance referred to in point 3.

2. Quality system

2.1. The manufacturer or his authorised representative shall lodge an application for assessment of his quality syst a notified body of his choice.

The application shall contain:

— the name and address of the manufacturer and, where appropriate, his authorised representative,

— the places of design, manufacture, inspection, testing and storage of the machinery,

— the technical file described in Annex VII, Part A, for one model of each category of machinery referred Annex IV which he intends to manufacture,

— the documentation on the quality system,

— a written declaration that the application has not been submitted to another notified body.

2.2. The quality system must ensure conformity of the machinery with the provisions of this Directive. All the elen requirements and provisions adopted by the manufacturer must be documented in a systematic and or manner, in the form of measures, procedures and written instructions. The documentation on the quality sy must permit a uniform interpretation of the procedural and quality measures, such as quality programmes, manuals and records.

It must contain, in particular, an adequate description of:

— the quality objectives, the organisational structure, and the responsibilities and powers of the management regard to the design and quality of the machinery,

— the technical design specifications, including standards that will be applied and, where the standards refern in Article 7(2) are not applied in full, the means that will be used to ensure that the essential health and requirements of this Directive are fulfilled,

— the design inspection and design verification techniques, processes and systematic actions that will be when designing machinery covered by this Directive,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and syste actions that will be used,

— the inspections and tests that will be carried out before, during and after manufacture, and the frequency which they will be carried out,

— the quality records, such as inspection reports and test data, calibration data, and reports on the qualifica of the personnel concerned,

— the means of monitoring the achievement of the required design and quality of the machinery, as well a effective operation of the quality system.

2.3. The notified body shall assess the quality system to determine whether it satisfies the requirements of point 2.

and the reasoned assessment decision.

3. Surveillance under the responsibility of the notified body

3.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out approved quality system.

3.2. The manufacturer shall, for inspection purposes, allow the notified body access to the places of design, m ture, inspection, testing and storage, and shall provide it with all necessary information, such as:

— the documentation concerning the quality system,

— the quality records provided for in that part of the quality system concerned with design, such as the re analyses, calculations, tests, etc.,

— the quality records provided for in that part of the quality system concerned with manufacture, such as tion reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

3.3. The notified body shall conduct periodic audits to make sure that the manufacturer is maintaining and apply quality system; it shall provide the manufacturer with an audit report. The frequency of the periodic audits such that a full reassessment is carried out every three years.

3.4. Moreover, the notified body may pay the manufacturer unannounced visits. The need for these additional vi their frequency will be determined on the basis of a visit monitoring system managed by the notified body. ticular, the following factors will be taken into account in the visits monitoring system:

— the results of previous surveillance visits,

— the need to monitor remedial measures,

— where appropriate, special conditions attaching to approval of the system,

— significant modifications in the organisation of the manufacturing process, measures or techniques.

On the occasion of such visits, the notified body may, if necessary, carry out tests or have them carried order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit and, if a test was carried out, with a test report.

4. The manufacturer or his authorised representative shall keep available for the national authorities, for a pe ten years from the last date of manufacture:

— the documentation referred to in point 2.1,

— the decisions and reports of the notified body referred to in point 2.4, third and fourth subparagraphs, points 3.3 and 3.4.

facturer, supplier or installer of machines which they inspect, nor the authorised representative of any of the parties. They shall not become involved, either directly or as authorised representatives, in the design, construction marketing or maintenance of the machines. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.

3. For each category of machinery for which it is notified, the body must possess personnel with technical knowledge and sufficient and appropriate experience to perform a conformity assessment. It must have the means necessary to complete the technical and administrative tasks connected with implementation of the checks in an appropriate manner; it must also have access to the equipment necessary for the exceptional checks.

4. The staff responsible for inspection shall have:

   — sound technical and vocational training,

   — satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,

   — the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.

5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.

6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law or the Member State itself is directly responsible for the tests.

7. The staff of the body shall be bound to observe professional secrecy with regard to all information obtained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.

8. Notified bodies shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or ensure that they know the situation in respect of relevant standards.

9. Member States may take all necessary measures they regard as necessary in order to ensure that, in the event of cessation of the activities of a notified body, the files of its customers are sent to another body or are made available to the Member State which has notified it.

Article 1(2)(a)	Article 2(a) and (b)
Article 1(2)(b)	Article 2(c)
Article 1(3)	Article 1(2)
Article 1(4)	Article 3
Article 1(5)	—
Article 2(1)	Article 4(1)
Article 2(2)	Article 15
Article 2(3)	Article 6(3)
Article 3	Article 5(1)(a)
Article 4(1)	Article 6(1)
Article 4(2), first subparagraph	Article 6(2)
Article 4(2), second subparagraph	—
Article 4(3)	—
Article 5(1), first subparagraph	Article 7(1)
Article 5(1), second subparagraph	—
Article 5(2), first subparagraph	Article 7(2) and (3)
Article 5(2), last subparagraph	—
Article 5(3)	Article 7(4)
Article 6(1)	Article 10
Article 6(2)	Article 22
Article 7(1)	Article 11(1) and (2)
Article 7(2)	Article 11(3) and (4)
Article 7(3)	Article 11(4)
Article 7(4)	Article 11(5)
Article 8(1), first subparagraph	Article 5(1)(e) and Article 12(1)
Article 8(1), second subparagraph	Article 5(1)(f)
Article 8(2)(a)	Article 12(2)
Article 8(2)(b)	Article 12(4)

Article 9(1), first subparagraph	Article 14(1)
Article 9(1), second subparagraph	Article 14(4)
Article 9(2)	Article 14(3) and (5)
Article 9(3)	Article 14(8)
Article 10(1 to 3)	Article 16(1) to (3)
Article 10(4)	Article 17
Article 11	Article 20
Article 12	Article 21
Article 13(1)	Article 26(2)
Article 13(2)	—
Article 14	—
Article 15	Atide 28
Article 16	Atide 29
Annex I — Preliminary observation 1	Annex I — General Principles poirt 2
Annex I — Preliminary observation 2	Annex I — General Principles poirt 3
Annex I — Preliminary observation 3	Annex I — General Principles poirt 4
Annex I, Part 1	Annex I, Part 1
Annex I, Section 1.1.	Annex I, Section 1.1.
Annex I, Section 1.1.1.	Annex I, Section 1.1.1.
Annex I, Section 1.1.2.	Annex I, Section 1.1.2.
Annex I, Section 1.1.2(d)	Annex I, Section 1.1.6.
Annex I, Section 1.1.3.	Annex I, Section 1.1.3.
Annex I, Section 1.1.4.	Annex I, Section 1.1.4.
Annex I, Section 1.1.5.	Annex I, Section 1.1.5.
Annex I, Section 1.2.	Annex I, Section 1.2.
Annex I, Section 1.2.1.	Annex I, Section 1.2.1.
Annex I, Section 1.2.2.	Annex I, Section 1.2.2.
Annex I, Section 1.2.3.	Annex I, Section 1.2.3.

Annex I, Section 1.3	Annex I, Section 1.3
Annex I, Section 1.3.1.	Annex I, Section 1.3.1.
Annex I, Section 1.3.2.	Annex I, Section 1.3.2.
Annex I, Section 1.3.3.	Annex I, Section 1.3.3.
Annex I, Section 1.3.4.	Annex I, Section 1.3.4.
Annex I, Section 1.3.5.	Annex I, Section 1.3.5.
Annex I, Section 1.3.6.	Annex I, Section 1.3.6.
Annex I, Section 1.3.7.	Annex I, Section 1.3.7.
Annex I, Section 1.3.8	Annex I, Section 1.3.8.
Annex I, Section 1.3.8 A	Annex I, Section 1.3.8.1.
Annex I, Section 1.3.8 B	Annex I, Section 1.3.8.2.
Annex I, Section 1.4.	Annex I, Section 1.4.
Annex I, Section 1.4.1.	Annex I, Section 1.4.1.
Annex I, Section 1.4.2.	Annex I, Section 1.4.2.
Annex I, Section 1.4.2.1.	Annex I, Section 1.4.2.1.
Annex I, Section 1.4.2.2.	Annex I, Section 1.4.2.2.
Annex I, Section 1.4.2.3.	Annex I, Section 1.4.2.3.
Annex I, Section 1.4.3.	Annex I, Section 1.4.3.
Annex I, Section 1.5.	Annex I, Section 1.5.
Annex I, Section 1.5.1.	Annex I, Section 1.5.1.
Annex I, Section 1.5.2.	Annex I, Section 1.5.2.
Annex I, Section 1.5.3.	Annex I, Section 1.5.3.
Annex I, Section 1.5.4.	Annex I, Section 1.5.4.
Annex I, Section 1.5.5.	Annex I, Section 1.5.5.
Annex I, Section 1.5.6.	Annex I, Section 1.5.6.
Annex I, Section 1.5.7.	Annex I, Section 1.5.7.
Annex I, Section 1.5.8.	Annex I, Section 1.5.8.
Annex I, Section 1.5.9.	Annex I, Section 1.5.9.

Annex I, Section 1.6.2.	Annex I, Section 1.6.2.
Annex I, Section 1.6.3.	Annex I, Section 1.6.3.
Annex I, Section 1.6.4.	Annex I, Section 1.6.4.
Annex I, Section 1.6.5.	Annex I, Section 1.6.5.
Annex I, Section 1.7.	Annex I, Section 1.7.
Annex I, Section 1.7.0.	Annex I, Section 1.7.1.1.
Annex I, Section 1.7.1.	Annex I, Section 1.7.1.2.
Annex I, Section 1.7.2.	Annex I, Section 1.7.2.
Annex I, Section 1.7.3.	Annex I, Section 1.7.3.
Annex I, Section 1.7.4.	Annex I, Section 1.7.4.
Annex I, Section 1.7.4.(b) and (h)	Annex I, Section 1.7.4.1.
Annex I, Section 1.7.4.(a) and (c) and (e) to (g)	Annex I, Section 1.7.4.2.
Annex I, Section 1.7.4.(d)	Annex I, Section 1.7.4.3.
Annex I, Part 2	Annex I, Part 2
Annex I, Section 2.1.	Annex I, Section 2.1.
Annex I, Section 2.1., paragraph 1	Annex I, Section 2.1.1.
Annex I, Section 2.1., paragraph 2	Annex I, Section 2.1.2.
Annex I, Section 2.2.	Annex I, Section 2.2.
Annex I, Section 2.2., paragraph 1	Annex I, Section 2.2.1.
Annex I, Section 2.2., paragraph 2	Annex I, Section 2.2.1.1.
Annex I, Section 2.3.	Annex I, Section 2.3.
Annex I, Part 3	Annex I, Part 3
Annex I, Section 3.1.	Annex I, Section 3.1.
Annex I, Section 3.1.1.	Annex I, Section 3.1.1.
Annex I, Section 3.1.2.	Annex I, Section 1.1.4.
Annex I, Section 3.1.3.	Annex I, Section 1.1.5.
Annex I, Section 3.2.	Annex I, Section 3.2.
Annex I, Section 3.2.1.	Annex I, Section 1.1.7. and 3.2.1.

Annex I, Section 3.4.	Annex I, Section 3.4.
Annex I, Section 3.4.1., paragraph 1	Annex I, Section 1.3.9.
Annex I, Section 3.4.1., paragraph 2	Annex I, Section 3.4.1.
Annex I, Section 3.4.2.	Annex I, Section 1.3.2.
Annex I, Section 3.4.3.	Annex I, Section 3.4.3.
Annex I, Section 3.4.4.	Annex I, Section 3.4.4.
Annex I, Section 3.4.5.	Annex I, Section 3.4.5.
Annex I, Section 3.4.6.	Annex I, Section 3.4.6.
Annex I, Section 3.4.7.	Annex I, Section 3.4.7.
Annex I, Section 3.4.8.	Annex I, Section 3.4.2.
Annex I, Section 3.5.	Annex I, Section 3.5.
Annex I, Section 3.5.1.	Annex I, Section 3.5.1.
Annex I, Section 3.5.2.	Annex I, Section 3.5.2.
Annex I, Section 3.5.3.	Annex I, Section 3.5.3.
Annex I, Section 3.6.	Annex I, Section 3.6.
Annex I, Section 3.6.1.	Annex I, Section 3.6.1.
Annex I, Section 3.6.2.	Annex I, Section 3.6.2.
Annex I, Section 3.6.3.	Annex I, Section 3.6.3.
Annex I, Section 3.6.3(a)	Annex I, Section 3.6.3.1.
Annex I, Section 3.6.3(b)	Annex I, Section 3.6.3.2.
Annex I, Part 4	Annex I, Part 4
Annex I, Section 4.1.	Annex I, Section 4.1.
Annex I, Section 4.1.1.	Annex I, Section 4.1.1.
Annex I, Section 4.1.2.	Annex I, Section 4.1.2.
Annex I, Section 4.1.2.1.	Annex I, Section 4.1.2.1.
Annex I, Section 4.1.2.2.	Annex I, Section 4.1.2.2.
Annex I, Section 4.1.2.3.	Annex I, Section 4.1.2.3.
Annex I, Section 4.1.2.4.	Annex I, Section 4.1.2.4.

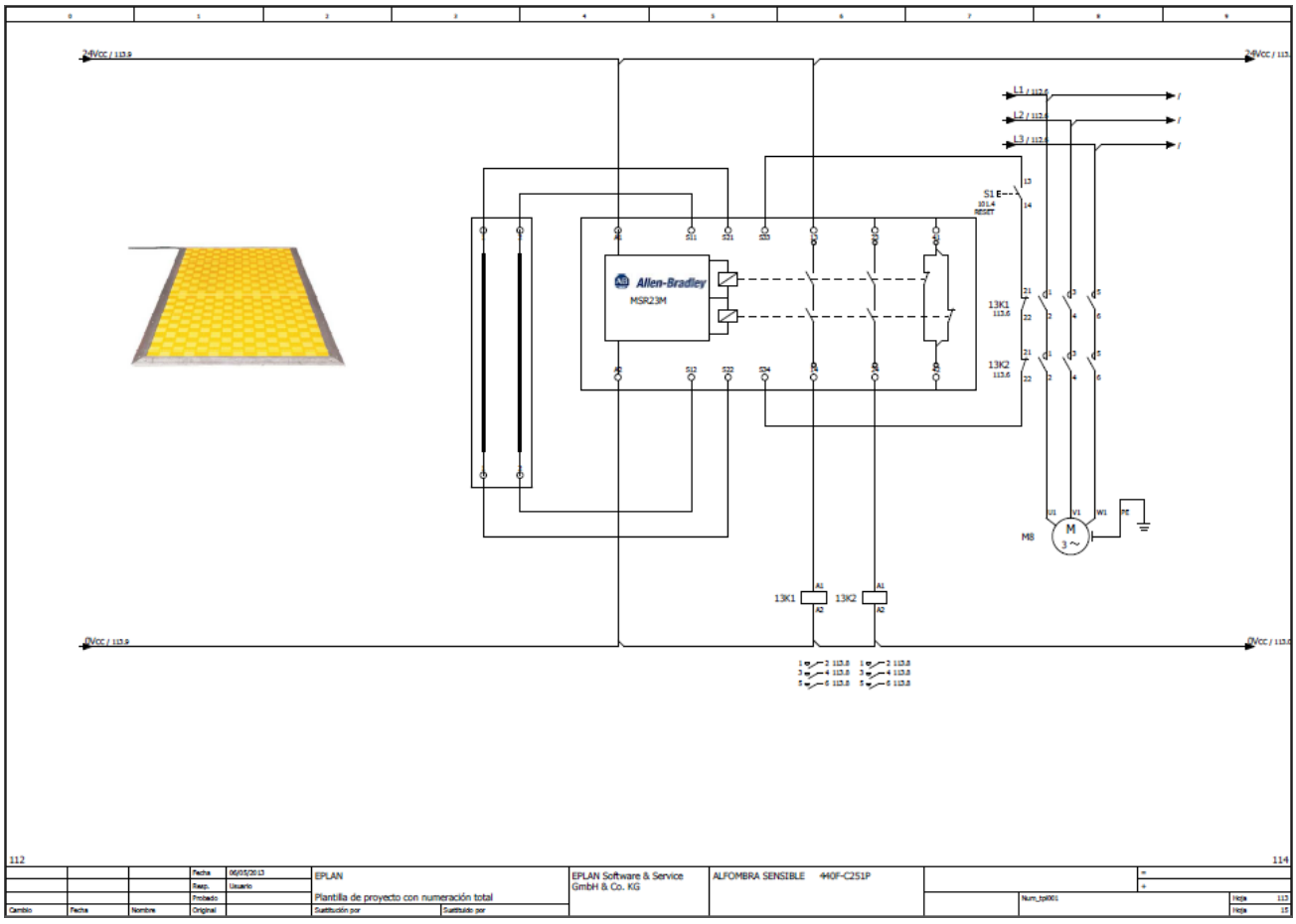
Annex I, Section 4.2.1.3.	Annex I, Section 4.2.1.
Annex I, Section 4.2.1.4.	Annex I, Section 4.2.2.
Annex I, Section 4.2.2.	Annex I, Section 4.2.3.
Annex I, Section 4.2.3.	Annex I, Sections 4.1.2.7. and 4.1.2.8.2.
Annex I, Section 4.2.4.	Annex I, Section 4.1.3.
Annex I, Section 4.3.	Annex I, Section 4.3.
Annex I, Section 4.3.1.	Annex I, Section 4.3.1.
Annex I, Section 4.3.2.	Annex I, Section 4.3.2.
Annex I, Section 4.3.3.	Annex I, Section 4.3.3.
Annex I, Section 4.4.	Annex I, Section 4.4.
Annex I, Section 4.4.1.	Annex I, Section 4.4.1.
Annex I, Section 4.4.2.	Annex I, Section 4.4.2.
Annex I, Part 5	Annex I, Part 5
Annex I, Section 5.1.	Annex I, Section 5.1.
Annex I, Section 5.2.	Annex I, Section 5.2.
Annex I, Section 5.3.	—
Annex I, Section 5.4.	Annex I, Section 5.3.
Annex I, Section 5.5.	Annex I, Section 5.4.
Annex I, Section 5.6.	Annex I, Section 5.5.
Annex I, Section 5.7.	Annex I, Section 5.6.
Annex I, Part 6	Annex I, Part 6
Annex I, Section 6.1.	Annex I, Section 6.1.
Annex I, Section 6.1.1.	Annex I, Section 4.1.1.(g)
Annex I, Section 6.1.2.	Annex I, Section 6.1.1.
Annex I, Section 6.1.3.	Annex I, Section 6.1.2.
Annex I, Section 6.2.	Annex I, Section 6.2.
Annex I, Section 6.2.1.	Annex I, Section 6.2.
Annex I, Section 6.2.2.	Annex I, Section 6.2.

Annex II, Parts A and B	Annex II, Part 1, Section A
Annex II, Part C	—
Annex III	Annex III
Annex IV.A.1 (1.1. to 1.4)	Annex IV.1 (1.1. to 1.4)
Annex IV.A.2	Annex IV.2
Annex IV.A.3	Annex IV.3
Annex IV.A.4	Annex IV.4 (4.1 and 4.2)
Annex IV.A.5	Annex IV.5
Annex IV.A.6	Annex IV.6
Annex IV.A.7	Annex IV.7
Annex IV.A.8	Annex IV.8
Annex IV.A.9	Annex IV.9
Annex IV.A.10	Annex IV.10
Annex IV.A.11	Annex IV.11
Annex IV.A.12 (first and second indent)	Annex IV.12 (12.1 and 12.2)
Annex IV.A.12 (third indent)	—
Annex IV.A.13	Annex IV.13
Annex IV.A.14, first part	Annex IV.15
Annex IV.A.14, second part	Annex IV.14
Annex IV.A.15	Annex IV.16
Annex IV.A.16	Annex IV.17
Annex IV.A.17	—
Annex IV.B.1	Annex IV.19
Annex IV.B.2	Annex IV.21
Annex IV.B.3	Annex IV.20
Annex IV.B.4	Annex IV.22
Annex IV.B.5	Annex IV.23
Annex V, Section 1	—

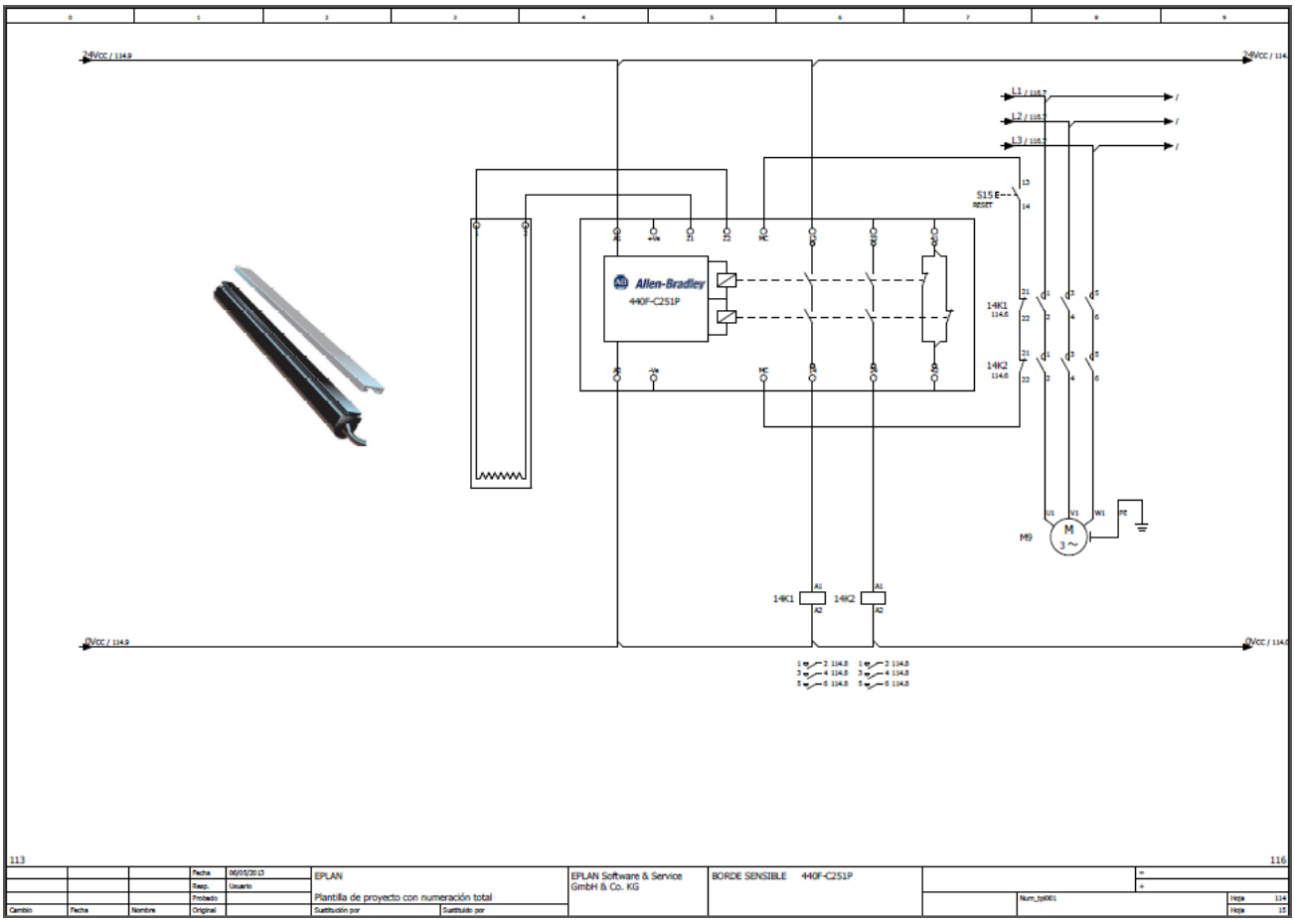
Annex V, Section 4 (b)	Annex VII, Part A. Section 2, first subparagraph
Annex V, Section 4(c)	Annex VII, Part A, Introduction
Annex VI, Section 1	Annex IX. Introduction
Annex VI, Section 2	Annex IX. Sections 1 and 2
Annex VI, Section 3	Annex IX. Section 3
Annex VI, Section 4, first subparagraph	Annex IX. Section 4, first subparagraph
Annex VI, Section 4, second subparagraph	Annex IX. Section 7
Annex VI, Section 5	Annex IX. Section 6
Annex VI, Section 6, first sentence	Annex IX. Section 5
Annex VI, Section 6, second and third sentences	Article 14(6)
Annex VI, Section 7	Annex IX. Section 8
Annex VI, Section 1	Annex XI. Section 1
Annex VI, Section 2	Annex XI. Section 2
Annex VI, Section 3	Annex XI. Section 3
Annex VI, Section 4	Annex XI. Section 4
Annex VI, Section 5	Annex XI. Section 5
Annex VI, Section 6	Annex XI. Section 6
Annex VI, Section 7	Annex XI. Section 7
Annex VII	—
Annex IX	—

ANEX II. ELECTRIC SCHEMAS. SAFETY CIRCUITS TYPES BASED ON ROCKWELL EQUIPMENT APPROVED, ESTABISHED BY STANDARD EN ISO 13849.

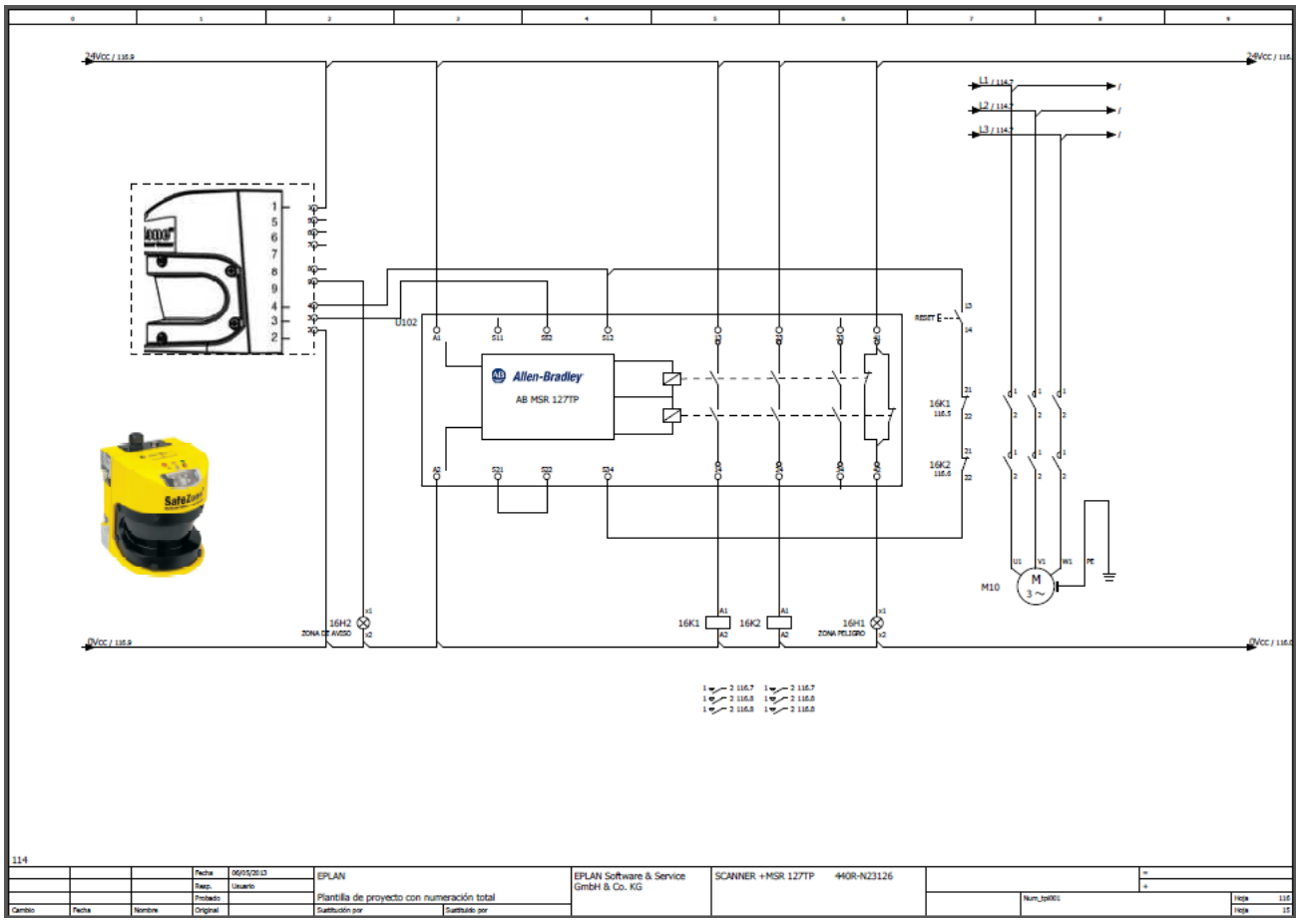
This picture shows the internal schema of a safety mat. Is possible to have all kind of schemas of most of products at Rockwell webpage and also at Allen-Bradley webpage too.



This schema shows the internal schema of a sensible edge.



This is the last schema that I show and is the internal schema of a laser scanner.


24Vcc / 116.9
24Vcc / 116.
L1 / 114.7
L2 / 114.7
L3 / 114.7
U102
Allen-Bradley
AB MSR 127TP
RESET E
16K1
116.5
16K2
116.6
M10
M
3 ~
16H2
ZONA DE AVISO
16K1
16K2
16H1
ZONA PELIGRO
0Vcc / 116.9
0Vcc / 116.
1 2 116.7 1 2 116.7
1 2 116.8 1 2 116.8
1 2 116.8 1 2 116.8
114
Fecha 05/03/2013
Resp. Usuario
Probado
Original
EPLAN
Plantilla de proyecto con numeración total
Sustitución por
Sustituido por
EPLAN Software & Service GmbH & Co. KG
SCANNER +MSR 127TP 440R-N23126
Num_tpl001
Hoja 114
Hoja 15
Cambio
Fecha
Nombre

ANEX III. REFERENCES

Rockwell Automation INK. Web page: http://www.rockwellautomation.com/

Spanish standardization standards web page, (AENOR): http://www.aenor.es/aenor/normas/buscadornormas/buscadornormas.asp

Spanish security legislation: http://www.f2i2.net/legislacionseguridadindustrial/Directiva.aspx?Directiva=2006/42/CE

Electrical standardization for electronic schemas: http://jfcgomez.webs.ull.es/Normalizacion%20IEC.pdf

Personal security at the use of industrial machines (legislation): http://es.rs-online.com/es/pdf/Schneider.pdf


SAVONIA